previously listed and evaluated as part of the Approach section. They will be listed as separate criteria to highlight the critical nature of these elements to project success. Bonus Points that appeared in prior years' FOAs will be removed from the evaluation criteria.

2. Titles and Assigned Weight: ANA would adjust the maximum point values of the evaluation criteria scores to further prioritize elements that are important to project monitoring and success. ANA proposes to use the following criteria values for the FY 2014 NABI FOA:

Need for Assistance—15 points;
Outcomes Expected—10 points;
Project Approach—20 points;
Organizational Capacity—25 points;
Objective Work Plan—20 points;
Budget and Budget Justification—10 points.

3. Scoring Guidance: ANA intends to provide guidance to reviewers to utilize the table below when allocating points for applications in order to ensure consistency and equivalence in scoring between different panels and panel reviewers. ANA would add the following table to all FY 2014 FOAs:

Excellent	93–100
Very Good	86–92
Good	78–85
Fair	70–77
Needs Significant Improvement	0–69

K. ANA Internal Review of Proposed Projects: ANA proposes to clarify the language in *Section V.2. Review and Selection Process* of all FY 2014 FOAs to clarify the scope of discretion to be exercised in making funding decisions as follows:

Based on the ranked order of applications, ANA staff will perform an internal review and analysis of the highest ranked applications in order to determine their consistency with the purposes of NAPA, all relevant statutory and regulatory requirements, and the requirements of this FOA. ANA's Commissioner has discretion to make all final funding decisions. In the exercise of such discretion, the Commissioner would consider whether the project:

1. Would further the purpose of this funding opportunity as described in *Section I. Description,* or is likely to be successful or cost effective based on what is submitted for evaluation in response to *Section IV.2. Project Description.*

2. Fails to provide documented commitment of non-federal cash contributions as described in *Section III.2. Cost Sharing or Matching* and *Section IV.2. Project Description, Commitment of Non-Federal Resources.*

3. Allows any one community, or region, to receive a disproportionate share of the funds available for award.

4. Is essentially identical or similar in whole, or in part, to previously funded projects proposed by the same applicant, or activities or projects proposed by a consortium that duplicates activities for which any consortium member also receives funding from ANA.

5. Provides couples or family counseling activities that are medically based.

6. Originated with and/or was designed by consultants who provide a major role for themselves and are not members of the applicant organization, tribe, or village.

7. Contains contingent activities that may impede, or indefinitely delay, the progress of the project.

8. Has the potential to cause unintended harm or that could negatively impact the safety or privacy of individuals.

9. May be used for the purpose of providing loan capital. Federal funds awarded under this FOA may not be used for the purpose of providing loan capital. This is not related to loan capital authorized under Sec. 803A of NAPA [42 U.S.C. 2991b–1(a)(1)] for the purpose of the Hawaiian Revolving Loan fund.

10. Includes human subject research as defined at 45 CFR 45.102(d) and (f).

L. Reporting: ANA would change the reporting requirement from quarterly to semi-annual for Objective Progress Reports (OPR) and Financial Status Reports (FSR). Therefore, grantees will be required to submit an OPR and an FSR every 6 months instead of every 3 months. Please note grantees will still be required to submit a Federal Financial Report—Federal Cash Transaction Report to the Division of Payment Management on a quarterly basis.

Lillian Sparks Robinson,

Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0191]

Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers.'' The purpose of the public workshop is to discuss the clinical and public health applications and performance validation of these devices, the quality criteria for establishing the accuracy of reference databases for regulatory use and ways to streamline clinical trials for microbial identification. This discussion is essential to establish the safety and effectiveness of high throughput sequencing devices when used to test human specimens or clinical isolates for the diagnosis of infectious diseases and detection of antimicrobial resistance markers.

DATES: *Date and Time:* The public workshop will be held on April 1, 2014, from 9 a.m. to 4:30 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Heike Sichtig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5269, Silver Spring, MD 20993–0002, email: *Heike.Sichtig@fda.hhs.gov.*

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on March 25, 2014. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations.

Registrants will receive confirmation once their registration has been accepted. Onsite registration on the day of the public workshop will be provided on a space-available basis beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: *susan.monahan@fda.hhs.gov* at least 7 days in advance of the workshop.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list). Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. If you are unable to register online, please contact Susan Monahan (301–796–5661, email: *susan.monahan@fda.hhs.gov*). Registration requests should be received by 5 p.m., March 25, 2014.

In advance of the meeting, registered attendees will receive a draft of FDA's proposed concept for the performance evaluation of High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers. Additional information, including a workshop agenda, will be available at a later date.

SUPPLEMENTARY INFORMATION:

I. Background

High throughput sequencing devices for the diagnosis of infectious diseases, including detection of antimicrobial resistance markers, are a new generation of diagnostic products that have the capability to simultaneously identify and differentiate a large number of microbial pathogens using a single clinical specimen or clinical isolate. These devices have already emerged as a critical tool in many research areas and soon they will become both a fixture in clinical microbiology reference laboratories and a routine part of diagnostic laboratory workflows. Use of this technology requires a process of sample/library preparation, sequencing, and output de-convolution/results interpretation. The identification of the organism or resistance marker is often based on genomic sequence information in comparison to reference databases that were created by the device manufacturer or are otherwise publicly available.

High throughput sequencing devices have the potential to dramatically change clinical microbiology. These diagnostic devices present several advantages, such as identifying potential disease etiology in situations where many different pathogens share a common clinical manifestation without the need for any a priori target specific information to select the appropriate test. However, the processes of selecting the methods used to establish and validate the performance of these devices to make informed clinical and public health decisions pose significant scientific and regulatory challenges.

The purpose of the public workshop is to discuss the implementation of high throughput sequencing devices for the diagnosis of infectious disease. Specifically, the FDA seeks input from clinical laboratories, infectious disease physicians, industry, government, academia, and other stakeholders on the following topics: Clinical applications and public health needs; device performance validation; reference databases; and ways to streamline clinical evaluations/trials for microbial identification. This information is viewed as essential in establishing the safety and effectiveness of high throughput sequencing devices when used for the clinical diagnosis of infectious diseases and markers of antimicrobial resistance from human specimens or clinical isolates.

II. Workshop Overview

This public workshop will consist of brief presentations providing information to frame the goals of the workshop, and an interactive discussion. The presentations will focus on current and anticipated uses for high throughput sequencing devices, a proposal for the performance evaluation approach preferred by FDA, and information on the criteria for acceptable reference databases. Following the presentations there will be a moderated discussion where the participants will be asked to provide their individual perspectives. The outcome of the meeting will be captured and released as a draft guidance document.

The draft guidance document is expected to be available at a later date. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov.* This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate workshop from the list).

III. Topics for Input

FDA will seek input on its proposed performance evaluation approach, which will include the following topics:

1. Clinical applications and public health needs: Identify specific applications where high throughput sequencing could be used for diagnosis of infectious diseases and markers of antimicrobial resistance from human specimens or clinical isolates.

2. Device validation: Develop and adapt standards for the microbial genome sequencing process (from sample collection to result reporting), discuss best practices for sample/library preparation, variant identification, genome annotation, output de-convolution/results interpretation, and reporting.

3. Reference databases: Develop quality criteria to establish accurate reference databases, methods for curating, maintaining, and updating these databases.

4. Streamline clinical evaluations/trials for microbial identification: Establish a new comparator paradigm for high throughput sequencing as the reference method to augment or replace existing reference testing methods.

IV. 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 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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