Dated: May 11, 2011.

Steven Hanmer,

OPRE Reports, Clearance Officer.

[FR Doc. 2011–12150 Filed 5–18–11; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0301]

Ultra High Throughput Sequencing for Clinical Diagnostic Applications—Approaches To Assess Analytical Validity; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting entitled "Ultra High Throughput Sequencing for Clinical Diagnostic Applications—Approaches To Assess Analytical Validity." The purpose of the public meeting is to discuss challenges in assessing analytical performance for ultra high throughput genomic sequencing-based clinical applications.

Date and Time: The public meeting will be held on June 23, 2011, from 8 a.m. to 6 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), 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*. The public meeting will also be available to be viewed online via Web cast.

Contact Person: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5668, Silver Spring, MD 20993–0002, 301–796–6206, e-mail: *zivana.tezak@fda.hhs.gov*.

Registration and Requests for Oral Presentations: If you wish to attend or view the Web cast of the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

Provide complete contact information for each attendee, including name, title, affiliation, e-mail, and telephone number. Registration requests should be received by June 9, 2011.

If you wish to make an oral presentation during the open comment session at the meeting, you must indicate this at the time of registration. FDA has included general discussion topics for comment in section III of this document, Topics for Input. You should also identify which discussion topic you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come, first-served basis. 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 they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

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, e-mail: *susan.monahan@fda.hhs.gov* at least 7 days in advance of the meeting.

Streaming Web Cast of the Public Meeting: There will be a registration process for the Web cast, and it will be on a first-come, first-served basis (*maximum capacity:* 900). If you have never attended a Connect Pro meeting before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public meeting to discuss a number of questions regarding appropriate approaches to assess analytical validity of ultra high throughput sequencing for clinical diagnostic applications. The deadline for submitting comments to be presented at this public meeting is June 9, 2011.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments on any discussion topic(s) to the open docket. The deadline for submitting comments to the docket is July 23, 2011. 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. 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, if responding to specific topics as outlined in section III of this document, please identify the topic 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.

SUPPLEMENTARY INFORMATION:

I. Background

Ultra high throughput genomic sequencing technologies are currently extensively used in research and are entering clinical diagnostic use; they are expected to bring transformative public health applications. In order to effectively utilize new sequencing technologies for clinical applications, appropriate evaluation tools (*e.g.,* standards, well established criteria) are needed to determine the accuracy of the results. Any regulatory strategy for clinical tests based on ultra high throughput genomic sequencing will benefit from novel and scientifically agreed-upon approaches to analytical validation. FDA is holding this public meeting to start discussion on approaches that can provide the most useful information in establishing safety and effectiveness of genomic sequencing technologies when used clinically.

This public meeting seeks input from academia, Government, industry, and other stakeholders on validation methodologies, materials, and bioinformatics approaches needed to address unique analytical validation requirements of ultra high throughput sequencing based molecular diagnostics and confirm the sequencing quality and the accuracy of the tests. The ultimate goal is to accelerate and support the introduction of safe and effective innovative diagnostics in public health applications.

II. Meeting Overview

The public meeting will consist of presentations providing background on

current and anticipated uses for sequencing technologies, an open public comment session, and roundtable discussions on selected topics. (See section III of this document.) The roundtable participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the public meeting will have an opportunity to listen to the roundtable discussion.

Additional information, including a meeting agenda, will be available on the Internet., immediately after publication of this **Federal Register** notice. 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 meeting from the list).

III. Topics for Input

FDA seeks input on the following issues:

1. Technical performance:
- Acceptance criteria,
- Validation samples/panels,
- Comparator/analytical standard.

2. Bioinformatics:
- Data format,
- Data analysis.

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, 12420 Parklawn Dr., rm. 1050, Rockville, MD 20857.

Dated: May 13, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–12310 Filed 5–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of a New System of Records

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is proposing a new system of records. The Countermeasures Injury Compensation Program (CICP), authorized by the Public Readiness and Emergency Preparedness Act (PREP Act), provides compensation to certain individuals for serious physical injuries or deaths resulting from the administration or use of pandemic, epidemic, or security countermeasures identified in declarations issued by the Secretary of the U.S. Department of Health and Human Services (the Secretary) pursuant to section 319F–3(b) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d–6d). The Secretary has issued several declarations specifying covered countermeasures, such as the pandemic 2009 H1N1 influenza vaccines, antiviral medications (*e.g.,* Tamiflu), anthrax vaccines, and smallpox vaccines. The PREP Act directs the Secretary to establish administrative procedures to compensate individuals who sustained serious injuries as the direct result of the administration or use of covered countermeasures. This system of records is required to comply with the implementation directives of the PREP Act, Public Law 109–148. The records will be used for the CICP's resource planning, administrative implementation (*e.g.,* making medical and/or financial eligibility determinations), compensating requesters, evaluation, scientific research, monitoring, and document storage purposes.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before June 20, 2011. As of the date of the publication of this Notice, HRSA has sent a Report of New System of Records to Congress and to the Office of Management and Budget (OMB). The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to the Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 11C–06, Rockville, Maryland 20857; telephone 1–800–ASK–HRSA (275–4772). This is a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Eastern Standard Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 11C–06, Rockville, Maryland 20857; telephone toll-free 1–800–ASK–HRSA (275–4772).

SUPPLEMENTARY INFORMATION: HRSA proposes to establish a new system of records: "The Countermeasures Injury Compensation Program, HHS/HRSA/HSB." The PREP Act which is a part of the "Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006" (Pub. L. 109–148), was enacted on December 30, 2005, and confers broad liability protections on covered persons, as defined in section 319F–3(i)(2) of the PHS Act, and authorizes the creation of a Countermeasures Injury Compensation Program (CICP or the Program) to compensate individuals injured by the administration or use of covered countermeasures, as defined in section 319F–3(i)(1) of the PHS Act, in the event of designated present or future public health emergencies. The Secretary has issued regulations for the administrative implementation of the Program at 42 CFR part 110.

The PREP Act provides the Secretary the authority, which was delegated by the Secretary on November 8, 2006 to the Administrator of HRSA, to compensate eligible individuals for covered injuries from a covered countermeasure.

Compensation benefits will be provided for eligible individuals who suffer serious physical injuries or death resulting from pandemic, epidemic, or security countermeasures such as vaccines identified in declarations issued by the Secretary under a "PREP Act declaration" issued in response to a current public health emergency, or to a credible risk that the disease, condition, or threat may in the future constitute such an emergency. The Secretary has issued several pandemic influenza declarations specifying