It is expected that ORR will continue to provide awards to the listed grantees for a 4-year project period. Grantees will be required to submit applications for noncompetitive awards for the subsequent years of the project period. Future noncompetitive awards will be based on the grantee's performance, the availability of funds, and the best interest of the Federal Government.

Statutory Authority: The Refugee Act of 1980 as amended, Wilson-Fish Amendment, Public Law 98–473, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–19923 Filed 8–19–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development'' that appeared in the **Federal Register** of December 29, 2016 (80 FR 81335). The document announced the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in Fiscal Year (FY) 2016. The document was published with the incorrect number of years in which CDRH committed to finalize, withdraw, re-open the comment period, or issue another draft guidance on the topic for 80 percent of the documents. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, December 29, 2015, in FR Doc. 2015–32726, the following correction is made:

1. On page 81336, in the third column, in the 13th sentence of the second paragraph under section II. *CDRH Guidance Development Initiative,* ''2 years'' is corrected to read ''3 years''.

Dated: August 16, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19874 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2473]

Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests.'' The purpose of this workshop is to obtain feedback on two FDA draft guidances, ''Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases'' and ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics'' that describes new approaches to regulate NGS-based tests.

DATES: The public workshop will be held on September 23, 2016, from 9 a.m.to 3 p.m. Submit either electronic or written comments on the public workshop by October 6, 2016.

ADDRESSES: The workshop will be held in Masur Auditorium at the NIH Campus, 9000 Rockville Pike, Bldg. 10, Bethesda, MD 20814. For parking and security information, please refer to the NIH Campus Visitor Information: *http://www.nih.gov/icd/od/ocpl/VIC/index.htm.*

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–N–2473 for ''Adapting Regulatory Oversight of Next Generation Sequencing-Based Tests.'' 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.

FOR FURTHER INFORMATION CONTACT: David Litwack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4548, Silver Spring, MD 20993, 301–796–6206, *ernest.litwack@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In Vitro diagnostic devices that utilize NGS technology to generate information on an individual's genome are rapidly transforming healthcare. As part of the Precision Medicine Initiative,[1] FDA is developing and implementing a novel framework for NGS test regulation that can accelerate innovation while assuring NGS-based test safety and effectiveness. To advance this effort, FDA published two draft guidances on July 8, 2016. The first, entitled ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics'', describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA's regulatory review of NGS-based tests. This draft guidance further outlines the process by which administrators of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases.

The second draft guidance document, entitled ''Use of Standards in the Food and Drug Administration's Regulatory Oversight of Next Generation Sequencing-Based In Vitro Diagnostics Used for Diagnosing Germline Diseases'', addresses DNA sequencing and whole exome sequencing NGS-based tests intended to aid in the diagnosis of individuals with suspected germline diseases or other conditions. This document provides recommendations for designing, developing, and validating NGS-based tests for germline diseases, and also discusses possible use of FDA-recognized standards for regulatory oversight of these tests. These recommendations are based on FDA's understanding of the tools and processes needed to run an NGS-based test along with the design and analytical validation considerations appropriate for such tests.

Neither draft guidance is final nor in effect at this time. The workshop announced in this document seeks to obtain public input on the proposals contained in the two draft guidances. Workshop material, including the draft guidances, can be accessed from the workshop Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

II. Topics for Discussion at the Public Workshop

This public workshop will consist of presentations that will frame the goals of the workshop followed by moderated discussions via panel sessions. The presentations and discussions will focus on the content of the draft guidances, as well as on additional questions that were posed in the Notices of Availability published in the **Federal Register** on July 8, 2016. These notices can be found at *https://federalregister.gov/a/2016-1233* and *https://federalregister.gov/a/2016-1270.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 13, 2016, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661, *susan.monahan@fda.hhs.gov,* no later than September 12, 2016.

To register for the public workshop, please visit FDA's Medical Devices News, Events, Workshops, and Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact David Litwack to register (see **FOR FURTHER INFORMATION CONTACT**). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. The Webcast link will be available on the registration Web site after September 13, 2016. To view the registration Web site, please visit FDA's Medical Devices News, Events, Workshops, and Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* Select this public workshop from the posted events list. FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. In addition to the subjects discussed in the two draft guidances, FDA has posed supplemental topics in the Notices of Availability for the draft guidances (see Supplementary Information). FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments, and request time for joint comments, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin,

[1] The Precision Medicine Initiative found on the White House's Web site at: *https://www.whitehouse.gov/precision-medicine.*

and will select and notify participants by September 14, 2016. All requests to make oral presentations must be received by September 13, 2016. If selected for presentation, any presentation materials must be emailed to David Litwack (see **FOR FURTHER INFORMATION CONTACT**) no later than September 16, 2016, at 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain feedback on its recently released draft guidance documents: ''Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing-Based In Vitro Diagnostics'' and ''Use of Standards in the Food and Drug Administration's Regulatory Oversight of Next Generation Sequencing-Based In Vitro Diagnostics Used for Diagnosing Germline Diseases''. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is October 6, 2016.

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 (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Dated: August 17, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19939 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

National Mammography Quality Assurance Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the National Mammography Quality Assurance Advisory Committee. This meeting was announced in the **Federal Register** of August 5, 2016. The amendment is being made to reflect a change in the **ADDRESSES** portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1552, Silver Spring, MD 20993–0002, *Sara.Anderson@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code MA. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 5, 2016 (81 FR 51918), FDA announced that a meeting of the National Mammography Quality Assurance Advisory Committee would be held on September 15, 2016. On page 51919, in the first column, in the **ADDRESSES** portion: Hilton Washington, DC/North, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900, is changed to read as follows: Gaithersburg Holiday Inn—Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20878. The hotel's telephone number is 301–948–8900.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 17, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–19957 Filed 8–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2474]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting associated with designation under the Minor Use and Minor Species Animal Health Act of 2004.

DATES: Submit either electronic or written comments on the collection of information by October 21, 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