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 noncompeting awards for the subsequent years of the project period. Future noncompeting awards will be based on the grantee’s performance, the availability of funds, and the best interest of the Federal Government.


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incorrect number of years in which CDRH committed to finalize, withdraw, re-open the comment period, or issue another draft guidance on the topic for 80 percent of the documents.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

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