[Federal Register Volume 80, Number 236 (Wednesday, December 9, 2015)]
[Notices]
[Pages 76500-76501]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2015-30937]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2881]

Standards-Based Approach to Analytical Performance Evaluation of Next Generation Sequencing in Vitro Diagnostic Tests; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of a public workshop that appeared in the Federal Register of September 9, 2015. In the notice of the public workshop, FDA requested comments on the workshop topics about the proposed standards-based regulatory strategy for next-generation sequencing (NGS) tests that produce results on variation in the human genome. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice of the public workshop published September 9, 2015. Submit either electronic or written comments by December 24, 2015.

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-2015-N-2881 for ``Standards-Based Approach to Analytical Performance Evaluation of Next-Generation Sequencing In Vitro Diagnostic 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

[[Page 76501]]

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: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4544, Silver Spring, MD 20993, 301-796-6206, zivana.tezak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 9, 2015 (80 FR 54292), FDA published a notice of a public workshop with a deadline of November 25, 2015, to request comments on the workshop topics about the proposed standards-based regulatory strategy for NGS tests that produce results on variation in the human genome. Comments on the public meeting topics will inform FDA's development of such strategies.

FDA is reopening the comment period for the notice of the public workshop until December 24, 2015. The Agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying decisionmaking on these important issues.

Dated: December 3, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015-30937 Filed 12-8-15; 8:45 am]

BILLING CODE 4164-01-P