Federal Register: Oversight of Laboratory Developed Tests; Public Meeting; Reopening of the Comment Period

U.S. Food & Drug Administration

[Federal Register: August 19, 2010 (Volume 75, Number 160)]
[Notices]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0274]

Oversight of Laboratory Developed Tests; Public Meeting;
Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 15, 2010, the comment period for the notice that published in the Federal Register of Thursday, June 17, 2010 (75 FR 34463). In the notice, FDA requested input and comments from interested stakeholders on the agency's oversight of laboratory developed tests (LDTs). FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments and information by September 15, 2010.

ADDRESSES: Submit electronic comments or information to http://www.regulations.gov [1]. Submit written comments or information to the Division of Dockets Management (HFA-305), Food and Drug Administration,

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5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Katherine Serrano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5613, Silver Spring, MD 20993, 301-796-6652, email: Katherine.serrano@fda.hhs.gov [3].

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 17, 2010 (75 FR 34463), FDA published a notice announcing a public meeting on July 19 and 20, 2010, and the opening of a public docket to seek input and comments from interested stakeholders to discuss the agency's oversight of LDTs. Interested persons were originally given until August 15, 2010, to comment on information.

II. Request for Comments

Following publication of the June 17, 2010, notice, FDA received a request to allow interested persons additional time to comment. The requester asserted that the initial time period was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010-20489 Filed 8-18-10; 8:45 am]
BILLING CODE 4160-01-S

SOURCE [4]

developed-tests-public-meeting-reopening-comment-period?qt-recent_content=0

Links:
[1] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov
[2] http://www.mdtmag.com/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=11661
[3] mailto://edocket.access.gpo.gov/2010/Katherine.serrano@fda.hhs.gov
[4] http://edocket.access.gpo.gov/2010/2010-20489.htm