

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0066]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of 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 May 2, 2011, the comment period for the notice announcing a meeting of the Molecular and Clinical Genetics Panel (the panel) of the Medical Devices Advisory Committee that published in the Federal Register of February 7, 2011 (76 FR 6623). In the notice, FDA requested public comment regarding the March 8 and 9, 2011, meeting of the panel to discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims. 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 May 2, 2011.

ADDRESSES: Submit electronic comments or information 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of February 7, 2011 (76 FR 6623), FDA published a notice announcing a meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee, and the opening of a public docket to seek input and comments from interested stakeholders to discuss scientific issues concerning DTC tests. Interested persons were given until March 1, 2011, to submit comments.

##### II. Request for Comments

Following publication of the February 7, 2011, notice, FDA received requests to allow interested persons additional time to comment. The requesters asserted that the initial time period was insufficient to allow potential respondents to thoroughly evaluate and assess pertinent issues. The Agency has considered the requests and is reopening the comment period until May 2, 2011.

##### III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the meeting. 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: March 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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