



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2187]

Identifying Potential Biomarkers for Qualification and Describing Contexts of Use to Address Areas Important to Drug Development; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice entitled “Identifying Potential Biomarkers for Qualification and Describing Contexts of Use to Address Areas Important to Drug Development; Request for Comments” that appeared in the Federal Register of February 13, 2015 (80 FR 8089). In the notice, FDA requested comments on identifying potential biomarkers for qualification and describing contexts of use to address areas important to drug development. The Agency is taking this action for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by May 15, 2015

ADDRESSES: Submit electronic comments 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.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4528, Silver Spring, MD 20993-0002, 301-796-7495.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 13, 2015 (80 FR 8089), FDA published a notice with a 60-day comment period to request comments on identifying potential biomarkers for qualification and describing contexts of use to address areas important to drug development. FDA is encouraging interested groups and individuals to submit information on specific medical and biological areas where novel biomarkers can be identified that would meaningfully advance drug development.

The current 60-day comment period does not allow sufficient time to obtain the broad public response that will inform FDA's Biomarker Qualification Program going forward. FDA is extending the comment period for an additional 30 days, thus extending the comment period to May 15, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying progress on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 30, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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