4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2537]

Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of draft guidance availability and public meeting; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of draft guidance availability and public meeting that appeared in the **Federal Register** of July 28, 2015, and August 7, 2015. In the notice of draft guidance availability and public meeting, FDA requested comments on a number of specific questions identified in the document. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of draft guidance availability and public meeting published July 28, 2015 (80 FR 44973) and August 7, 2015 (80 FR 47493). Submit either electronic or written comments by November 27, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA-2015-D-2537) for this notice of draft guidance availability and public meeting. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or 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: Lesley DeRenzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5161, Silver Spring, MD 20993-0002, 240-402-4612.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 28, 2015, and August 7, 2015, FDA published a notice of draft guidance availability and public meeting with a 60-day comment period and requested

comments on a number of specific questions identified throughout the document. Comments on the notice of draft guidance availability and public meeting will inform FDA's development and planned implementation of a quality metrics program launched under the authority of the Federal Food, Drug, and Cosmetic Act.

FDA is extending the comment period for an additional 60 days, until November 27, 2015. The Agency believes that an additional 60-day extension of the comment period for the notice of draft guidance availability and public meeting will allow adequate time for interested persons to submit comments without significantly delaying Agency decisionmaking 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). You should annotate and organize your comments to identify the specific questions or topic to which they refer. 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: August 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-21149 Filed: 8/25/2015 08:45 am; Publication Date: 8/26/2015]