



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2015-N-0540]

Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of public hearing that appeared in the Federal Register of March 27, 2015. In the notice of public hearing, FDA requested comments on a number of specific questions identified in the document. 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 on the notice of public hearing published March 27, 2015 (80 FR 16327), and extended on June 10, 2015 (80 FR 32868). Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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-N-0540 for this notice of public hearing. 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: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6214, Silver Spring, MD 20993-0002, 301-796-2895.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 27, 2015, FDA published a notice of public hearing with a 60-day comment period following the public hearing and requested comments on a number of

specific questions identified throughout the document. Comments on the notice of public hearing will inform FDA's decision about whether and how to adjust the current enforcement policies for drug products labeled as homeopathic to reflect changes in the homeopathic product marketplace over the last approximately 25 years. In the Federal Register of June 10, 2015, in response to requests for an extension to allow interested persons additional time to submit comments, FDA extended the original comment period for 60 days, until August 21, 2015.

FDA is reopening the comment period for an additional 60 days, until [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Agency believes that reopening the comment period for an additional 60 days for the notice of public hearing 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: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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