4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0202]

Over-The-Counter Drug Monograph System--Past, Present, and Future; Public Hearing; 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 the comment period for the notice of public hearing, published in the Federal Register of February 24, 2014 (79 FR 10168), requesting comment on how to improve or alter the current Over-the-Counter (OTC) Monograph Process for reviewing nonprescription drugs marketed under the OTC Drug Review. FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER].

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: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20903-0002, 301-796-3519, mary.gross@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 24, 2014 (79 FR 10168), FDA announced a public hearing to obtain input on the OTC Drug Review (sometimes referred to as the OTC Monograph Process, OTC Monograph, or OTC Drug Review). As stated in the Federal Register notice, FDA has been assessing the OTC Monograph Process and, in particular, has been considering how effectively the monograph system is functioning in today's world, 40 years after its inception, from the scientific, policy, and process perspectives. In the February 24, 2014, notice of public hearing, FDA announced it was soliciting comments about whether and how to modernize the process for the future. The public hearing was held to obtain information and comments from the public on the strengths and weaknesses of the current OTC Monograph Process, and to obtain and discuss ideas about modifications or alternatives to this process. Interested persons were originally given until May 12, 2014, to comment on the OTC Monograph Process.

II. Request for Comments

On our own initiative, we are reopening the comment period to allow interested persons additional time to comment 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 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 identified by the topic to which they refer (see 79 FR 10168 at 10171, section III). 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: June 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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