



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-2013-N-0521]

Menthol in Cigarettes, Tobacco Products; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the Federal Register of July 24, 2013 (78 FR 44484). In the ANPRM, FDA requested comments, including comments on FDA's preliminary evaluation, and data, research, or other information that may inform regulatory actions that FDA might take with respect to menthol in cigarettes. 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 ANPRM. Submit either electronic or written comments by November 22, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0521, 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 or CD-ROM 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 Agency name and Docket No. FDA-2013-N-0521 for this rulemaking. 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 “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: Lauren Berkowitz or Annette L. Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 24, 2013 (78 FR 44484), FDA published an ANPRM with a 60-day comment period to request comments on FDA’s preliminary evaluation, and data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes.

The Agency has received comments requesting a 60-day extension of the comment period for the ANPRM. These comments convey concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to questions raised in the ANPRM. FDA has also received comments opposing an extension of the current comment period on the grounds that ample time has been given to comment on the issues raised in the ANPRM.

FDA has considered the requests and is extending the comment period for the ANPRM for 60 days, until November 22, 2013. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential regulatory action 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: September 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-22015 Filed 09/10/2013 at 8:45 am; Publication Date: 09/11/2013]