4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2014-N-0189]

RIN 0910-AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for a proposed rule that appeared in the Federal Register of April 25, 2014. In the proposed rule, FDA requested comments, including comments on FDA's proposed options for regulation of cigars, regulatory approach to electronic cigarettes and other non-combustible tobacco products, pathways to market for proposed deemed tobacco products, and compliance dates for certain provisions, among other issues. 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 proposed rule that appeared in the Federal Register of April 25, 2014 (79 FR 23141). Submit either electronic or written comments by August 8, 2014.

ADDRESSES: You may submit comments, identified by Agency name, Docket No. FDA-2014-N-0189, and/or Regulatory Information Number (RIN) 0910-AG38, 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 Agency name, Docket No. FDA-2014-N-0189, and RIN 0910-AG38 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: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 25, 2014 (79 FR 23141), FDA published a proposed rule with a 75-day comment period (ending July 9, 2014) to request comments, including comments on FDA's proposed options for regulation of cigars, regulatory approach to electronic cigarettes and other non-combustible tobacco products, pathways to market for proposed deemed tobacco products, and compliance dates for certain provisions, among other issues.

The Agency has received multiple requests to extend the comment period for the proposed rule including over 2,000 form letters as part of a write-in campaign to request additional time to comment. The requests conveyed concern that the current 75-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to questions raised in the proposed rule. 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 proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for an additional 30 days, until August 8, 2014. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

A. General Information About Submitting 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 Agency name, Docket No. FDA-2014-N-0189, and RIN 0910-AG38.

B. Public Availability of Comments

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. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on http://www.regulations.gov. This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field titled "Category (Required)," on the "Your Information" page on http://www.regulations.gov. For this proposed rule, however, FDA will not be following this general practice. Instead, FDA will post on http://www.regulations.gov comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on http://www.regulations.gov if you include that information in the body of your comments. For electronic comments submitted to http://www.regulations.gov, FDA will post the body of your comment on http://www.regulations.gov along with your state/province and

country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on http://www.regulations.gov, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

Dated: June 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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