4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-2011-N-0467]

RIN 0910-AG43

# Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products; 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 until January 19, 2012, for an advance notice of proposed rulemaking (ANPRM) that was published in the Federal Register of September 9, 2011 (76 FR 55835). In that document, FDA requested comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, email, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients. The Agency is extending the comment period in response to a request to give interested parties additional time to comment.

DATES: Submit either electronic or written comments by January 19, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0467 and/or RIN number 0910-AG43, 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:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, 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-2011-N-0467 and Regulatory Information Number (RIN 0910-AG43) 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:

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SUPPLEMENTARY INFORMATION:

## I. Background

In the Federal Register of September 9, 2011 (76 FR 55835), FDA issued an ANPRM to obtain information related to the regulation of non-face-to-face sale and distribution of tobacco products and the advertising, promotion, and marketing of tobacco products. FDA took this action as part of its implementation of the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31, 123 Stat. 1776). FDA requested comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, email, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients. FDA intends to use the information submitted in response to the ANPRM to inform its regulation of the sale and distribution of tobacco products through a non-face-to-face exchange and the advertising, promotion, and marketing of tobacco products. FDA provided a 90-day comment period (i.e., until December 8, 2011) for the ANPRM.

FDA has received a request to extend the comment period. The request stated that additional time is needed to coordinate factual information and policy positions with a large number of States on several of the questions in the ANPRM. The request noted that their comments will be more thorough and of more assistance to FDA if more time is available to develop them.

FDA has considered the request and is extending the comment period an additional 6 weeks, until January 19, 2012. We believe that the additional time will provide interested parties sufficient time to submit comments on the ANPRM.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this ANPRM. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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