



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

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the potential regulation of menthol in cigarettes. FDA is also making available its preliminary scientific evaluation of public health issues related to the use of menthol in cigarettes. The preliminary scientific evaluation indicates there is likely a public health impact of menthol in cigarettes. This ANPRM is seeking comments, including 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.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: 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

The Family Smoking Prevention and Tobacco Control Act, enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the

authority to regulate tobacco products (Public Law 111-31, 123 Stat. 1776). Among other things, section 907(e) of the FD&C Act (21 U.S.C 387g(e)) requires FDA's Tobacco Products Scientific Advisory Committee (TPSAC) to submit a report and recommendations to the Secretary of Health and Human Services (the Secretary of HHS) on the impact of the use of menthol in cigarettes on the public health, including use among children, African Americans, Hispanics, and other racial/ethnic minorities.

TPSAC has submitted the report to HHS, available at

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>. In addition, the nonvoting industry

representatives of TPSAC submitted a separate document reflecting the industry perspective, available at

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf>. Two cigarette manufacturers have

challenged FDA's ability to rely on TPSAC's menthol report, and that case is currently pending (Lorillard, Inc. v. FDA, No. 11-440 (D.D.C.)).

Experts within FDA's Center for Tobacco Products (CTP) also initiated an independent evaluation of the available science related to the impact of the use of menthol in cigarettes on public health including peer-reviewed literature, secondary data analyses, and independent CTP analyses of relevant large data sets. This preliminary independent evaluation is entitled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes" (the evaluation) (Ref. 1). The evaluation has been peer reviewed, and the peer review report is available on FDA's Web site at

<http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAsse>

[ssments/ucm079120.htm](https://www.fda.gov/oc/assessments/ucm079120.htm). FDA is also making available an addendum with articles published since the evaluation was submitted for peer review in 2011 (Ref. 2).

As discussed previously, the FD&C Act provides FDA with authority to regulate tobacco products. This includes authority to adopt a tobacco product standard under section 907 of the FD&C Act if the Secretary of HHS finds that a tobacco product standard is appropriate for the protection of public health and includes authority to amend an existing product standard. In making such a finding, the Secretary of HHS must consider scientific evidence concerning: (1) The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the product standard; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products. The FD&C Act also provides FDA with authority to, by regulation, require restrictions on the sale and distribution of a tobacco product (section 906(d)(1) of the FD&C Act (21 U.S.C. 387f(d)(1))). The restrictions on sale and distribution of a tobacco product may include restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary of HHS determines such regulation would be appropriate for the public health.

FDA intends to use the information submitted in response to this Federal Register document, FDA's preliminary independent scientific evaluation, and other appropriate information to inform its thinking about options for regulating menthol in cigarettes.

II. Request for Comments and Information

FDA is seeking comments, including comments on its preliminary evaluation, and data, research (e.g., published or unpublished studies, case studies), and any other information related

to the following questions. Please explain your responses and provide any evidence or other information supporting your responses to the following questions:

A. Tobacco Product Standards

1. Should FDA consider establishing a tobacco product standard for menthol in menthol cigarettes? If so, what allowable level of menthol (e.g., maximum or minimum) would be appropriate for the protection of the public health?

2. Rather than a tobacco product standard for menthol in menthol cigarettes, should FDA consider a tobacco product standard for any additive, constituent, artificial or natural flavor, or other ingredient that produces a characterizing flavor of menthol in the tobacco product or its smoke?

3. If a tobacco product standard for menthol in menthol cigarettes were to be established, should FDA consider issuing regulations to address menthol in other tobacco products besides cigarettes? If so, what other tobacco products with menthol should be regulated: All tobacco products, just all combusted tobacco products, or some other category or group of tobacco products? If not, what distinctions should be made between products?

4. If a product standard prohibiting or limiting menthol were to be established, what length of time should manufacturers be provided to achieve compliance with the standard? If a product standard prohibiting or limiting menthol were to be established, would a stepped approach in which the level of menthol was gradually reduced be appropriate for the protection of the public health?

5. If a product standard limiting menthol were to be established, are there alternatives that could be substituted by manufacturers to maintain the effect or appeal of menthol to menthol cigarette smokers and potential initiators? If so, what are these substitutes? Should they be

regulated if menthol is regulated; and if so, how should they be regulated? If not, what distinctions should be made between menthol and potential substitutes?

B. Sale and Distribution Restrictions

1. Should FDA consider establishing restrictions on the sale and/or distribution of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?

2. Should FDA consider establishing restrictions on the advertising and promotion of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?

C. Other Actions and Considerations

1. Are there other tobacco product standards, regulatory, or other actions that FDA could implement that would more effectively reduce the harms caused by menthol cigarette smoking and better protect the public health than the tobacco product standards or regulatory actions discussed in the preceding questions?

2. To the extent that you have identified a tobacco product standard or other regulatory action in response to the prior questions, please provide additional information and comments on:

2.1 Is compliance with the tobacco product standard or other regulatory action you identified technically achievable?

2.2 How FDA would structure a corresponding rule to maximize compliance, facilitate enforcement, and otherwise maximize public health benefits?

3. If menthol cigarettes could no longer be legally sold, is there evidence that illicit trade in menthol cigarettes would become a significant problem? If so what would be the impact of

any such illicit trade on public health? How would any such illicit trade compare to the existing illicit trade in cigarettes?

4. What additional information and research beyond that described in the evaluation is there on the potential impact of sale and distribution restrictions of menthol cigarettes on specific subpopulations, such as those based on racial, ethnic, socioeconomic status, and sexuality/gender identity?

5. To what extent are you aware of current (within the past 5 years) advertising and/or promotion of menthol cigarettes that have targeted specific communities, subpopulations, and locations, beyond that described in the evaluation?

6. Might any current advertising or other marketing or public statements concerning menthol cigarettes, or menthol in other tobacco products, constitute reduced risk claims?

III. 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>.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. CTP, Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes.

2. CTP, Reference Addendum to the “Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes, 2013.”

Dated: July 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-17805 Filed 07/23/2013 at 8:45 am; Publication Date: 07/24/2013]