

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2018-N-0128]

Nicotine Steering Committee; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to receive suggestions, recommendations, and comments on topics or policy issues for consideration by FDA's Nicotine Steering Committee (NSC). FDA would like to receive feedback from interested parties, including academic institutions, regulated industries, patient representatives, and other interested organizations. These comments will help the Agency identify and address priorities related to the use of therapeutic nicotine for combustible tobacco product cessation.

DATES: Submit either electronic or written comments by April 16, 2018.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-0128 for "Recommendations and Comments for the Food and Drug Administration Nicotine Steering Committee." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Allison Hoffman, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1314, Silver Spring, MD 20993, 301-796-9203, OMPTFeedback@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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The NSC was established in November 2017 to help develop and implement nicotine policy and regulation. The primary focus of the NSC is on the use of therapeutic nicotine for combustible tobacco product cessation. The NSC is comprised of senior leaders from the Center for Drug Evaluation and Research, the Center for Tobacco Products, and the Office of the Commissioner. The NSC will ensure alignment of FDA's Centers and facilitate consensus and development of unified FDA positions on cross-cutting issues related to nicotine policy and regulation. Additional staff from the Centers and other FDA offices provide expertise as needed for specific policy topics under consideration. While there are various other mechanisms available to raise issues for Agency consideration, by establishing this public docket FDA seeks to provide a mechanism for the public to recommend specific topics for direct, collective engagement and consideration by the NSC. The Agency believes that this process will also further enhance transparency in FDA's approach to policy development and implementation.

II. Establishment of a Public Docket and Request for Comments

The docket is being established to solicit suggestions, recommendations, and comments relating to the use of therapeutic nicotine for combustible tobacco product cessation that may warrant consideration by the NSC (see Staff Manual Guide 2010.20, FDA Nicotine Steering Committee¹). Topic suggestion submissions should describe the following: (1) The nicotine policy issue recommended for discussion (e.g., clarifying previous advice or precedents on a specified therapeutic nicotine product policy topic, reconciling seemingly differing perspectives within

¹ <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM594385.pdf>.

FDA or between FDA and regulated industry on a specified therapeutic nicotine product policy topic); (2) the rationale for doing so, including why direct engagement by the NSC would be appropriate/helpful; (3) recommendations on how the nicotine policy issue could be addressed; and (4) existing policy documents (*e.g.*, final guidance) relevant to the nicotine product policy issue. Note that policy issues concerning any draft guidance or proposed rule should be submitted to the docket for that draft guidance or rulemaking.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment. In general, policy decisions reached by the NSC are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

Dated: February 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03341 Filed 2-16-18; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2017-0637; FRL-9974-62—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Emissions Statement Requirement for the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Maryland. This revision fulfills Maryland's emissions statement requirement for the 2008 ozone national ambient air quality standard (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before March 22, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R03-OAR-2017-0637 at <http://www.regulations.gov>, or via email to spielberger.susan@epa.gov. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted,

comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Gavin Huang, (215) 814-2042, or by email at huang.gavin@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On March 27, 2008, EPA strengthened the ozone standard from 0.08 to 0.075 parts per million (ppm). 73 FR 16436. On May 21, 2012, EPA designated areas as nonattainment for the 2008 ozone NAAQS, including the Baltimore and Washington, DC-MD-VA areas, which include the following counties in Maryland: Anne Arundel, Baltimore, Baltimore City, Carroll, Harford, Howard, Cecil, Calvert, Charles, Frederick, Montgomery, and Prince George's Counties. See 40 CFR 81.321.

Additionally, Maryland is located in the ozone transport region (OTR) established by Congress in section 184 of the CAA. Pursuant to section 184(b)(2), any stationary source that emits or has the potential to emit at least 50 tons per year (tpy) of volatile organic compounds (VOC) shall be considered a major stationary source and subject to the requirements which would be applicable to major stationary sources if the area were classified as a moderate nonattainment area. See CAA section 184. Thus, states within the OTR are subject to plan (or SIP) requirements in CAA section 182(b) applicable to moderate nonattainment areas. Also, section 182(f)(1) of the CAA requires that the plan provisions required for major stationary sources of VOC also apply to major stationary sources of

oxides of nitrogen (NO_x) for states with moderate (or worse) ozone nonattainment areas. A major stationary source of NO_x is defined as stationary facility or source of air pollutants which directly emits, or has the potential to emit 100 tpy or more of NO_x. See CAA section 302(j).

Section 182 of the CAA identifies additional plan submissions and requirements for ozone nonattainment areas. Specifically, section 182(a)(3)(B) of the CAA requires that states develop and submit rules which establish annual reporting requirements for certain stationary sources. Sources that are within marginal (or worse) ozone nonattainment areas must annually report the actual emissions of NO_x and VOC to the state. However, states may waive sources that emit under 25 tpy of NO_x and VOC if the state provides an inventory of emissions from such class or category of sources. See CAA section 182(a)(3)(B)(ii).

In summary, because Maryland is located in the OTR, sources that are located in ozone attainment areas and emit above 50 tpy of VOC or 100 tpy of NO_x are considered major sources and subject to the requirements of major stationary sources in moderate (or worse) nonattainment area, such as an emissions statement submission as required by CAA section 182(a)(3)(B). See CAA sections 182(f) and 184(b)(2). Sources that are located in designated marginal (or worse) nonattainment areas must submit an emissions statement as required by CAA section 182(a)(3)(B). As stated previously, states may waive sources under that emit 25 tpy of NO_x and 25 tpy of VOC threshold if the state provides an inventory of emissions from such class or category of sources as required by CAA sections 172 and 182.¹ See section 182(a)(3)(B)(ii).

On September 25, 2017, the State of Maryland, through the Maryland Department of the Environment (MDE), submitted a SIP revision to satisfy the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2008 ozone NAAQS.

II. Summary of SIP Revision and EPA Analysis

On October 12, 1994 (59 FR 51517), EPA approved Maryland's SIP submittal that satisfies CAA section 182(a)(3)(B). Maryland's emissions reporting requirements are codified in Maryland regulation COMAR 26.11.01.05-1

¹ For further information on the emissions statement reporting requirements, see "Guidance on the Implementation of an Emission Statement Program (July 1992)" https://www.epa.gov/sites/production/files/2015-09/documents/emission_statement_program_zypdf.pdf, pp. 5-9.