



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0227]

Tobacco Product Manufacturing Practice; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting public input on updated recommendations for regulations on good manufacturing practice for electronic nicotine delivery systems (ENDS) that were submitted to FDA by a group of 13 tobacco companies (tobacco companies' ENDS recommendations). FDA is providing an opportunity for interested parties to comment on the tobacco companies' ENDS recommendations.

DATES: Submit electronic or written comments on the tobacco companies' ENDS recommendations by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2013-N-0227 for "Tobacco Product Manufacturing Practice; Establishment of a Public Docket." Received comments, those filed in a timely manner (see ADDRESSES), 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." The Agency 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 docket, 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: Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing. The new provisions include, among other things, the authority to issue regulations related to tobacco product manufacturing practice in order to protect the public health and to assure that tobacco products are in compliance with the FD&C Act. Specifically, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) provides that in applying manufacturing restrictions to tobacco, the Secretary shall prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and

controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology.

On May 10, 2016, FDA published a final rule entitled "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (81 FR 28974) (the deeming rule) that became effective on August 8, 2016. Under the deeming rule, newly deemed tobacco products, including ENDS, are now subject to the provisions of the Tobacco Control Act that apply automatically to all products that meet the statutory definition of a tobacco product in section 201(rr) of the FD&C Act (21 U.S.C. 321(r)).

On January 10, 2012, industry stakeholders submitted recommendations for good manufacturing practice requirements (and a draft preamble) for tobacco products that were immediately subject to FDA's jurisdiction when the Tobacco Control Act went into effect. This January 10, 2012, letter was posted to this Docket No. FDA-2013-N-0227 on March 12, 2013, as part of a request for comments on the recommendations contained in the letter. On June 7, 2017, a group of 13 tobacco companies submitted to FDA: (1) recommendations for good manufacturing practice requirements for ENDS and (2) an attachment letter with a meeting request (Ref. 1). The tobacco companies' ENDS recommendations are intended to supplement an earlier letter dated January 10, 2012. According to the June 7, 2017, letter, the tobacco companies' ENDS recommendations seek to account for the differences in manufacturing ENDS.

FDA is providing an opportunity for all interested parties to comment only on the tobacco companies' ENDS recommendations submitted on June 7, 2017.

II. References

The following reference has been placed on display in the Dockets Management Staff (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and is available electronically at <https://www.regulations.gov>.

1. Proposed Good Manufacturing Practices Regulation to Account for FDA's Deeming Regulation and Request for Meeting, submitted to FDA, June 7, 2017.

Dated: November 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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