



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-D-0661]

### Modifications to Compliance Policy for Certain Deemed Tobacco Products; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance for industry entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products" that appeared in the *Federal Register* of March 14, 2019. In the draft guidance for industry, FDA requested comments on changes to the compliance policies for premarket review requirements for certain deemed tobacco products and how FDA intends to prioritize its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization. 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**DATES:** FDA is extending the comment period on the draft guidance for industry published March 14, 2019 (84 FR 9345). Submit either electronic or written comments by April 30, 2019, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You must submit your comment(s) on or before April 30, 2019, to ensure that the Agency considers your comment(s) before it begins work on the final version of the guidance.

#### *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-2019-D-0661 for "Modifications to Compliance Policy for Certain Deemed Tobacco Products." 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." 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 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:** Gerie Voss, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of March 14, 2019, FDA published a draft guidance for industry with a 30-day comment period to request comments on changes to the compliance policies for premarket review requirements and how FDA plans to prioritize its enforcement resources with regard to certain deemed tobacco products in the United States that do not have the required FDA premarket authorization for marketing. Comments on the draft guidance for industry will inform how FDA intends to finalize the guidance.

The Agency has received requests for an extension of the comment period for the draft guidance for industry. The requests conveyed concern that the current 30-day comment period does not allow sufficient time to develop a response to the draft guidance for industry.

FDA has considered the requests and is extending the comment period for the draft guidance for industry for 15 days, until April 30, 2019. The Agency believes that a 15-day

extension allows adequate time for interested persons to submit comments without significantly delaying the process to finalize this guidance.

Dated: April 3, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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