4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1132

[Docket No. FDA-2016-N-2527]

Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule that appeared in the Federal Register of January 23, 2017. In the proposed rule, FDA requested comments on its proposal to establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. The Agency is also providing notice of a typographical error in a formula in the Laboratory Information Bulletin (LIB) titled, "Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC-MS/MS" (LIB No. 4620, January 2017). In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review", the Agency is also taking this opportunity to provide notice that, as with all regulatory actions subject to such memorandum, this proposed rule is being reviewed consistent with the memorandum.

DATES: FDA is extending the comment period on the proposed rule published January 23, 2017 (82 FR 8004). Submit either electronic or written comments by July 10, 2017[. Late,

untimely filed comments will not be considered. Electronic comments must be submitted on or before July 10, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [July 10, 2017. 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.

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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-N-2527 for "Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products." Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beth Buckler or Colleen Lee, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, rm. G335, Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 23, 2017, FDA published a proposed rule with a 75-day comment period to request comments on our proposal to establish a limit for NNN in finished smokeless tobacco products. Comments on the proposed rule will inform FDA's rulemaking to establish a tobacco product standard for NNN.

The Agency has received requests for a 75-day extension of the comment period for the proposed rule. Each request expressed concern that the current 75-day comment period does not allow the public sufficient time to develop thoughtful responses to the proposed rule.

The Agency also has received a request to clarify a formula in the Laboratory Information Bulletin (LIB) titled, "Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC-MS/MS" (LIB No. 4620, January 2017). Upon further review, FDA has determined that the formula for converting NNN on a wet weight basis to a dry weight basis contains a typographical error -- some of the terms and variables in the numerator and denominator were inadvertently switched. FDA has revised the LIB to correct this error (LIB No. 4623, March 2017, available at https://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM546874.pdf). We note that the typographical error in the LIB did not affect our calculations in the preamble of the proposed rule or the supporting analyses.

FDA has considered the requests and is extending the comment period for the proposed rule for 90 days, until [July 10, 2017. The 90-day extension will provide additional time for interested persons to submit comments on all aspects of the proposed rule, including whether the approach proposed in the rule is appropriate.

Dated: March 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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