4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA-2019-N-3065]

RIN 0910-AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; additional materials; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the proposed rule that appeared in the *Federal Register* of August 16, 2019. The Agency is providing additional information in the docket and reopening the public comment period for 15 days to afford the public an opportunity to comment on this additional information.

DATES: FDA is reopening the comment period on the proposed rule published August 16, 2019 (84 FR 42754). Submit either electronic or written comments by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. 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-2019-N-3065 for "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements." 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 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: Courtney Smith, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 16, 2019 (84 FR 42754), FDA published a proposed rule that will, once finalized, implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, will specify the color graphics that must accompany the new textual warning statements. The proposed new textual warnings include some that are specified in the Tobacco Control Act and some new textual warning statements that FDA is proposing to promote greater public understanding of the negative health consequences of cigarette smoking. FDA's proposed cigarette warning rule was issued pursuant to a court-ordered schedule (see *Am. Acad. Pediatrics*

v. *FDA*, No. 16-cv-11985, 2019 U.S. Dist. LEXIS 34946 (D. Mass. Mar. 5, 2019)), which, among other things, requires FDA to submit the proposed rule for publication by August 15, 2019, and to submit the final rule by March 15, 2020.

As described in FDA's proposed rule, in developing the new cigarette health warnings, FDA undertook a science-based, iterative research process. The proposed rule was informed by two quantitative consumer research studies, "Experimental Study on Warning Statements for Cigarette Graphic Health Warnings" (Office of Management and Budget (OMB) control number 0910-0848) and "Experimental Study of Cigarette Warnings" (OMB control number 0910-0866), that assessed the extent to which FDA's proposed warnings increase understanding of the negative health consequences of cigarette smoking. As part of developing and informing its research, FDA conducted various qualitative focus groups and interviews ("qualitative studies") to test and refine image concepts and obtain feedback on which textual statements should be selected for further study. Qualitative studies are based on small samples, have exploratory aims and objectives, should not be viewed as nationally representative, and do not yield data that can be generalized. FDA did not originally include the qualitative study reports in the docket as FDA did not rely on these studies as part of the rulemaking. However, because the qualitative studies were used to inform further research, namely, the quantitative consumer research studies, FDA is making these additional materials available as well.

FDA is placing additional materials in the docket and reopening the comment period for the proposed rule for 15 days to allow comment on the additional materials. The Agency believes that a 15-day reopening allows adequate time for interested persons to submit comments on this additional information without significantly delaying rulemaking.

FDA is adding the following materials to the docket for the proposed rule:

- "Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions" (July 2015) (OMB control number 0910-0674, "Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions")
- "Memorandum of Findings from Cognitive Testing of Spanish Warning Labels" (March 2016)
- "FDA Graphic Health Warning Image Concept Testing" (June 2016) (OMB control number 0910-0796, "Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions")
- "Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images" (April 2018) (OMB control number 0910-0796, "Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images")

Dated: November 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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