



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA-2020-D-0988]

Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled "Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide." This guidance is intended to help small businesses understand and comply with FDA's document entitled "Tobacco Products: Required Warnings for Cigarette Packages and Advertisements," which establishes new required cigarette health warnings for cigarette packages and advertisements.

DATES: March 18, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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-2020-D-0988 for "Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide." 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.govinfo.gov/content/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Belcher or Annette Marthaler, 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.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide." FDA is issuing this guidance to help small businesses understand and comply with the final rule, codified at 21 CFR part 1141, entitled "Tobacco Products: Required Warnings for Cigarette Packages and Advertisements", that establishes new required cigarette health warnings for cigarette packages and advertisements and is published elsewhere in this edition of the *Federal Register*. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require each cigarette package and

advertisement to bear one of the new required warnings. Additionally, as required under the FCLAA, the rule establishes marketing requirements that include the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121).

II. Significance of Guidance

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on assisting small businesses to understand and comply with FDA's final rule, "Tobacco Products: Required Warnings for Cigarette Packages and Advertisements." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to collections of information described in FDA's rule on "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," which this guidance is intended to interpret. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The information collection provisions in the final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either <https://www.regulations.gov> or

<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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