



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-5364]

Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised final guidance for industry entitled “Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).” This is a revision to the third edition of this final guidance, which issued in February 2021, and is intended to assist those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing content, timing, and other recommendations related to those submissions. FDA is revising this guidance to reflect the May 21, 2021, court order that postponed the effective date of the final rule entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” to July 13, 2022. Pursuant to the court order, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by the recommended submission date, which is currently September 13, 2021.

DATES: The announcement of the revised final guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit 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-2019-D-5364 for "Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)."

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 office between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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, 240-402-7500.

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

Submit written requests for single copies of this 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 may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

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, 1-877-287-1373, email:

AskCTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised final guidance for industry entitled “Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).” The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the Federal Cigarette Labeling and Advertising Act of 1965 (Pub. L. 89-92) (FCLAA) to direct FDA to issue regulations requiring each cigarette package and advertisement to bear a new textual warning label statement accompanied by color graphics depicting the negative health consequences of smoking (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). The Tobacco Control Act also modified the requirements of the FCLAA regarding the submission of cigarette plans for the random and equal display and distribution of required warnings on cigarette packages and quarterly rotation of required warnings in cigarette advertisements. It also requires that such cigarette plans be submitted to FDA for review and approval, rather than to the Federal Trade Commission.

In the *Federal Register* of March 18, 2020, FDA issued a final rule entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” (85 FR 15638). The rule specifies the color graphics that must accompany the new textual warning label statements and establishes marketing requirements for cigarette packages and advertisements. The marketing requirements include, among other things, submission of a cigarette plan that provides for the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements, as described under section 4 of FCLAA.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.¹ On May 8, 2020, the Court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.² On December 2, 2020, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days.³ On March 2, 2021, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days.⁴ On May 21, 2021, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days.⁵ The new effective date of the final rule is July 13, 2022. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of the final rule is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date. As such, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by September 13, 2021.

¹ *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20-cv-00176 (E.D. Tex. filed April 3, 2020).

² *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

³ *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs’ motion and postponing effective date), Doc. No. 80.

⁴ *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. March 2, 2021) (order granting Plaintiffs’ motion and postponing effective date), Doc. No. 89.

⁵ *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs’ motion and postponing effective date), Doc. No. 91.

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 regarding the submission of plans for cigarette packages and cigarette 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 1141.10 have been approved under 0910-0877.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at <https://www.regulations.gov>, <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>, and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: June 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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