Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday - Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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Contains Nonbinding Recommendations

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Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The Food and Drug Administration (FDA or Agency) is issuing this guidance to provide information regarding FDA's enforcement policy for the final rule[2], "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," which established new required cigarette health warnings for cigarette packages and advertisements.

FDA is implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2)). FDA made this determination because we need to communicate this enforcement policy in a timely manner given that the final rule is now in effect due to developments in litigation, as explained below.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance was prepared by the Office of Compliance and Enforcement and the Office of Regulations in the Center for Tobacco Products at FDA.

[2] For the purposes of this guidance, "rule" or "final rule" refers to the final rule published in the *Federal Register* at 85 FR 15638 (March 18, 2020), codified at 21 CFR part 1141.

II. BACKGROUND

In the *Federal Register* of March 18, 2020, FDA issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) 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 (FCLAA) (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. Pursuant to section 201(b) of the Tobacco Control Act, the rule was published with an effective date of June 18, 2021, 15 months after the date of publication of the final rule.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[3] The District Court issued multiple orders postponing the effective date of the rule, the most recent of which postponed the effective date to November 6, 2023.[4] On December 7, 2022, the District Court issued an order vacating the rule.[5] On March 21, 2024, the U.S. Court of Appeals for the Fifth Circuit issued an opinion reversing the District Court and concluding that FDA's rule is consistent with the First Amendment.[6] The opinion remanded the case to the District Court for consideration of plaintiffs' remaining claims. A petition for rehearing en banc was denied on May 21, 2024,[7] and the court's mandate issued on May 29, 2024.[8] Accordingly, the rule is no longer vacated. Because the November 6, 2023, date in the District Court's most recent order postponing the effective date has passed, the rule is now in effect.

The final rule established new required warnings to appear on cigarette packages and advertisements that consist of new textual warning statements accompanied by concordant photorealistic images depicting the negative health consequences of smoking. These warnings must appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements. Additionally, the final rule requires the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotation of the required warnings for cigarette advertisements. A tobacco product manufacturer, distributor, or retailer is required to submit a plan for the random and equal display and distribution of the required warnings on packages and the quarterly rotation in advertisements for approval by FDA (referred to as cigarette plans) and must maintain a copy of the FDA-approved plan and make the plan available for inspection and copying by officers and employees of FDA.

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[3] *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).
[4] *R.J. Reynolds Tobacco Co.*, No. 6:20–cv–00176 (E.D. Tex. Nov. 7, 2022) (order postponing effective date), Doc. No. 104. *See also* "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date," 87 FR 72384 (Nov. 25, 2022).
[5] *R.J. Reynolds Tobacco Co.*, No. 6:20–cv–00176 (E.D. Tex. Dec. 7, 2022) (opinion and order; final judgment), Docs. No. 106; 107.
[6] *R.J. Reynolds Tobacco Co. et al., v. United States Food and Drug Administration et al.*, No. 23-40076 (5th Cir. Mar. 21, 2024) (panel opinion), Doc. No. 140-1.
[7] *R.J. Reynolds Tobacco Co. et al.*, No. 23-40076 (5th Cir. May 21, 2024) (order denying petition for rehearing), Doc. No. 162-2.
[8] *R.J. Reynolds Tobacco Co. et al.*, No. 23-40076 (5th Cir. May 29, 2024) (mandate), Doc. No. 163-2.

III. ENFORCEMENT POLICY

FDA recognizes that some manufacturers, distributors, and retailers already may have begun to prepare to implement the rule's requirements. For instance, some manufacturers, distributors, and retailers already have submitted and obtained approval of cigarette plans. Even so, FDA recognizes that entities may need time to implement the rule's requirements. For example, those remaining entities that do not already have approved cigarette plans may need time to submit and obtain FDA approval of their cigarette plans. In addition, entities may need time to work with printers to replace the Surgeon General's warnings with the rule's required warnings as outlined in their approved plans. Other related compliance efforts may also require time for implementation.

Further, while the rule was published with a 15-month effective date, the sequence of events described above resulted in the rule having its effective date postponed multiple times, being vacated, and then being reinstated. Under these unusual circumstances, FDA believes that it is reasonable to exercise enforcement discretion to provide for an orderly transition period. And FDA believes that it is reasonable for the length of that orderly transition period to be similar to the 15-month compliance period originally contemplated by the Tobacco Control Act, before that timing was disrupted by litigation. Regulated entities that are prepared to come into full compliance with the rule more quickly are encouraged to do so.

FDA intends to exercise enforcement discretion and generally not enforce requirements of the final rule for 15 months after the issuance of this guidance, until December 12, 2025. FDA also intends to exercise enforcement discretion and generally not enforce requirements of the final rule for an additional 30 days, until January 12, 2026, with respect to products manufactured before December 12, 2025. These time periods are consistent with section 201(b) of the Tobacco Control Act and the effective date of the final rule upon its publication.[9] As FDA recommended at the time of publication of the final rule, FDA recommends that entities that do not already have approved cigarette plans submit such plans as soon as possible, but in any event within 5 months of the issuance of this guidance, by February 10, 2025. Early submission will facilitate timely FDA review.

Entities that previously submitted cigarette plans[10] to FDA (whether those plans already received approval or are still pending) need not resubmit their plans unless they wish to make changes to

[9] During this same period, which is consistent with sections 103(q)(5) and 301 of the Tobacco Control Act, FDA likewise intends to exercise enforcement discretion and generally not enforce requirements in sections 903(a)(2) and 920(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that are tied to the effective date of the rule. The relevant requirements are, in short, that cigarette packages bear a label containing (A) the name and place of business of the tobacco product manufacturer, packer, or distributor; (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; (C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and (D) the statement "Sale only allowed in the United States." FD&C Act §§ 903(a)(2) and 920.

[10] Please see FDA's guidance, "Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)," to assist persons submitting cigarette plans for cigarette packages and cigarette advertisements. The guidance provides recommendations related to 21 CFR 1141 and the FCLAA requirements regarding the submission of cigarette plans for cigarette packages and cigarette advertisements.

those plans. If an entity wishes to make a change to an approved cigarette plan, it should file a supplement to such plan for FDA's review. If an entity wishes to make a change to a plan that is pending FDA review, it should file an amendment to such plan for FDA's review.

IV. DOCUMENT HISTORY

September 2024 – First edition of guidance issued.