U.S. FOOD & DRUG ADMINISTRATION

September 12, 2024

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA or the Agency) has issued a final guidance for industry: "*Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements.*" This guidance describes FDA's enforcement policy for the final rule, "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," which established new required health warnings for cigarette packages and advertisements. The guidance is intended to assist entities required to comply with the rule and is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-required-warnings-cigarette-packages-and-advertisements.

Consistent with our good guidance practices (GGP) regulation (21 CFR 10.115), we are implementing this guidance immediately and without prior comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because FDA needs to communicate its enforcement policy in a timely manner given that the rule is now in effect due to developments in litigation, as explained below. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's GGP regulation.

In the *Federal Register* of March 18, 2020, FDA issued a final rule establishing new required 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. In accordance with 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.[1] 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.[2] On December 7, 2022,

[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.*, 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).

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the District Court struck down the rule.[3] 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.[4] 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,[5] and the court's mandate issued on May 29, 2024.[6] This reinstated the final rule. 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.

As explained in the guidance, 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 the 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.[7] As FDA recommended

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[3] *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.

[4] *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.

[5] *R.J. Reynolds Tobacco Co.*, No. 23-40076 (5th Cir. May 21, 2024) (order denying petition for rehearing), Doc. No. 162-2.

[6] *R.J. Reynolds Tobacco Co.*, No. 23-40076 (5th Cir. May 29, 2024) (mandate), Doc. No. 163-2.

[7] 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.

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 the guidance, by February 10, 2025.

The guidance represents FDA's current thinking 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.

If you have any questions regarding the guidance, please contact Megan Hicks at CTP-TribalLiaison@fda.hhs.gov.

For general questions regarding FDA's activities with federally recognized Tribal Nations, or to submit formal correspondence to the Agency, please contact the Agency's Intergovernmental Affairs (IGA) staff at IGA@fda.hhs.gov. IGA serves as FDA's primary liaison with Tribal Nations and officials and is a dedicated resource for tribal officials to interface with the Agency.

FDA encourages you to stay informed about further developments related to tobacco products through the CTP website located at http://www.fda.gov/TobaccoProducts or by signing up for CTP email newsletters at https://www.fda.gov/tobacco-products/ctp-newsroom/subscribe-fda-center-tobacco-products-ctp-email-newsletters. You may also contact the Center via telephone at 1-877-CTP-1373, via email at AskCTP@fda.hhs.gov, or via mail at 10903 New Hampshire Ave., Silver Spring, MD 20993.

We look forward to continuing to strengthen the relationship between FDA and Tribal Nations to protect and advance public health among American Indian and Alaska Native tribes.

Sincerely,

Brian A. King, PhD, MPH
Director, Center for Tobacco Products