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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2024–D–3742]

Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled ''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 cigarette health warnings for cigarette packages and advertisements. The guidance is intended to assist entities required to comply with the rule.

DATES: The announcement of the guidance is published in the **Federal Register** on September 13, 2024.

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–2024–D–3742 for ''Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements.'' 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, 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 document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''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'' (85 FR 15638, March 18, 2020; codified at 21 CFR part 1141), which established new required cigarette health warnings for cigarette packages and advertisements. The guidance is intended to assist entities required to comply with the rule. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public 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 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) (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 statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. 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 in accordance with an FDA-approved plan (referred to as cigarette plans), consistent with the Tobacco Control Act. 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.[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, the District Court issued an order vacating 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] Accordingly, the rule is no longer vacated. Because the November 6, 2023, date in the District Court's most recent order postponing the rule's effective date has passed, the rule is now in effect.

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. In the guidance, FDA sets out its enforcement policy for the final rule. As discussed in the guidance, 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. 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, by February 10, 2025.

The guidance represents the current thinking of FDA 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1141.10 have been approved under OMB control number 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/rules-regulations-and-guidance/guidance,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20850 Filed 9–12–24; 8:45 am]

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[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. November 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 (November 25, 2022).

[3] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. December 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. March 21, 2024) (panel opinion), Doc. No. 140–1.

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

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

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 501

Reporting, Procedures and Penalties

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Interim final rule; request for comments.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is issuing this interim final rule to amend the Reporting, Procedures and Penalties Regulations (the ''Regulations''), extending recordkeeping requirements for certain transactions from five to 10 years, consistent with the statute of limitations