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]

BILLING CODE 4164–01–P

[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

for violations of certain sanctions administered by the Office of Foreign Assets Control (OFAC).

DATES:

Effective date: This interim final rule is effective March 12, 2025.

Comments due date: Written comments may be submitted on or before October 15, 2024.

ADDRESSES: You may submit comments via the following methods, electronic is preferred:

Federal eRulemaking Portal: www.regulations.gov. Follow the instructions on the website for submitting comments. Refer to Docket Number OFAC–2024–0004.

Mail: Office of Foreign Assets Control, U.S. Department of the Treasury, Treasury Annex/Freedman's Bank Building, 1500 Pennsylvania Avenue NW, Washington, DC 20220. Refer to Docket Number OFAC–2024–0004.

Instructions: All submissions received must include the agency name and the **Federal Register** Doc. number that appears at the end of this document. All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; Assistant Director for Compliance, 202–622–2490 or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Background

On April 24, 2024, the President signed into law the 21st Century Peace through Strength Act, Public Law 118–50, div. D (the ''Act''). Section 3111 of the Act extended from five years to 10 years the statute of limitations for civil and criminal violations of the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (IEEPA), and the Trading with the Enemy Act, 50 U.S.C. 4301 *et seq.* (TWEA). Prior to the Act's enactment, civil enforcement actions brought by OFAC under IEEPA or TWEA were subject to the five-year statute of limitations set forth in 28 U.S.C. 2462. The new 10-year statute of limitations—codified at 50 U.S.C. 1705(d) and 4315(d)—became effective upon the President's signature of the Act on April 24, 2024. This new 10-year statute of limitations applies to any violation that was not time-barred at the time of its enactment. Consequently, OFAC may now commence an enforcement action for civil violations of IEEPA- or TWEA-based sanctions prohibitions within 10 years of the latest date of the violation if such date was after April 24, 2019. As set forth in the Act, the commencement of a civil enforcement action includes the issuance of a pre-penalty notice or a finding of violation.

To match the new statute of limitations period, OFAC is publishing this interim final rule extending from five years to 10 years the recordkeeping requirements codified at 31 CFR 501.601, paragraph IV.B of appendix A to part 501, and 515.572. OFAC is soliciting public comments for 30 days on this interim final rule.

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Public Participation

Because the amendment of the Regulations is a rule of agency procedure and involves a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the collections of information related to 31 CFR 501.601, paragraph IV.B of appendix A to part 501, and 515.572 have been previously approved by the Office of Management and Budget (OMB) under control number 1505–0164. This final rule modifies the requirements for recordkeeping under these sections by increasing the period for recordkeeping to 10 years from five years to align with a statutory amendment. This modification to this collection of information, as well as an unrelated consolidation of certain OFAC information collections, will be submitted to OMB for review under control number 1505–0164. Written comments and recommendations for the modified collection can be submitted by visiting *https://www.reginfo.gov/public/do/PRAMain.* Find this document by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. Comments are welcome and must be received by November 13, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number. The likely filers and record-keepers affected by these collections of information contained in 31 CFR part 501 are financial institutions, business organizations, nonprofit organizations, individuals, households, non-governmental organizations, and legal representatives.

The burden of the recordkeeping requirement imposed by this rule is minimal because the records required to be maintained are likely maintained under standard business practice. The recent increase in the recordkeeping period to 10 years from five years could impose a temporary incremental burden on recordkeepers while they update their recordkeeping practices and adjust storage requirements to maintain records for a longer period of time. Accordingly, the total burden for this collection is estimated to be:

Estimated Number of Respondents: 2,505,086.

Frequency of Response: When requested by OFAC.

Estimated Total Number of Annual Responses: 2,505,086.

Estimated Time per Response: No additional time to retain records for additional time.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

List of Subjects in 31 CFR Part 501

Administrative practice and procedure, Banks, Banking, Exports, Foreign trade, Licensing and registration, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, OFAC amends 31 CFR parts 501 and 515 as follows:

PART 501—REPORTING, PROCEDURES AND PENALTIES REGULATIONS

■ 1. The authority citation for part 501 continues to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2332d, 2339B; 19 U.S.C. 3901–3913; 21 U.S.C. 1901–1908; 22 U.S.C. 287c, 2370(a), 6009, 6032, 7205, 8501–8551; 31 U.S.C. 321(b); 50 U.S.C. 1701 *et seq.,* 4301–4341; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note).

Subpart C—Reports

■ 2. Revise and republish § 501.601 to read as follows:

§ 501.601 Records and recordkeeping requirements.

Except as otherwise provided, every person engaging in any transaction subject to the provisions of this chapter shall keep a full and accurate record of each such transaction engaged in, regardless of whether such transaction is effected pursuant to license or otherwise, and such record shall be available for examination for at least 10 years after the date of such transaction. Except as otherwise provided, every person holding property blocked pursuant to the provisions of this chapter or funds transfers retained pursuant to § 596.504(b) of this chapter shall keep a full and accurate record of such property, and such record shall be available for examination for the period of time that such property is blocked and for at least 10 years after the date such property is unblocked.

■ 3. Revise paragraph IV.B of appendix A to part 501 to read as follows:

Appendix A to Part 501—Economic Sanctions Enforcement Guidelines

* * * * *

IV. * * *

B. The late filing of a required report, whether set forth in regulations or in a specific license, may result in a civil monetary penalty in an amount up to $3,550, if filed within the first 30 days after the report is due, and a penalty in an amount up to $7,104 if filed more than 30 days after the report is due. If the report relates to blocked assets, the penalty may include an additional $1,422 for every 30 days that the report is overdue, up to 10 years.

* * * * *

PART 515—CUBAN ASSETS CONTROL REGULATIONS

■ 4. The authority citation for part 515 continues to read as follows:

Authority: 22 U.S.C. 2370(a), 6001–6010, 7201–7211; 31 U.S.C. 321(b); 50 U.S.C. 4301 *et seq.;* Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); 22 U.S.C. 6021–6091; Pub. L. 105–277, 112 Stat. 2681; Pub. L. 111–8, 123 Stat. 524; Pub. L. 111–117, 123 Stat. 3034; E.O. 9989, 13 FR 4891, 3 CFR, 1943–1948 Comp., p. 748; Proc. 3447, 27 FR 1085, 3 CFR, 1959–1963 Comp., p. 157; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614.

■ 5. Revise and republish paragraph (b)(1) of § 515.572 as follows:

§ 515.572 Provision of travel, carrier, other transportation-related, and remittance forwarding services.

* * * * *

(b) * * *

(1) Persons subject to U.S. jurisdiction providing services authorized pursuant to paragraphs (a)(1) through (4) of this section must retain for at least 10 years from the date of the transaction a certification from each customer indicating the section of this part that authorizes the person to travel or send remittances to Cuba. In the case of a customer traveling under a specific license, the specific license number or a copy of the license must be maintained on file with the person subject to U.S. jurisdiction providing services authorized pursuant to this section.

* * * * *

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2024–20674 Filed 9–11–24; 8:45 am]

BILLING CODE 4810–AL–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2024–0255; FRL–12071–02–R1]

Air Plan Approval; New Hampshire; Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving most of a State Implementation Plan (SIP) revision submitted by the State of New Hampshire. This revision updates the State regulation containing ambient air quality standards. EPA is approving all the State's updated standards, except the primary annual fine particle ($PM_{2.5}$) standard, which we are conditionally approving because it does not match EPA's current National Ambient Air Quality Standard for $PM_{2.5}$. This action is being taken in accordance with the Clean Air Act.

DATES: This rule is effective on October 15, 2024.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2024–0255. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Branch, Air and Radiation Division (Mail Code 5–MD), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts, 02109–3912, (617) 918–1684; *simcox.alison@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. Background and Purpose

On July 11, 2024 (89 FR 56825), EPA published a Notice of Proposed Rulemaking (NPRM) for the State of New Hampshire.

The NPRM proposed approval of New Hampshire's update to its Env-A 300, ''Ambient Air Quality Standards'' (AAQS). The formal SIP revision was submitted by the state on December 22, 2022.

EPA determined that the state's updated AAQS are consistent with the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 for all standards except the $PM_{2.5}$ primary annual standard, which EPA strengthened subsequent to New Hampshire's SIP submittal (89 FR 16202).