

■ 12. In § 356.12, revise paragraph (a)(5) to read as follows:

§ 356.12 Sanctions for violation of a protective order or disclosure undertaking.

(a) * * *

(5) Required to destroy and certify to the Department the destruction of all material previously provided by the investigating authority, and all other materials containing the proprietary information, such as briefs, notes, or charts based on any such information received under a protective order or a disclosure undertaking.

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■ 13. In § 356.14, revise paragraphs (d)(2) and (4) to read as follows:

§ 356.14 Report of violation and investigation.

* * * * *

(d) * * *

(2) Failure to follow the detailed procedures outlined in the protective order for safeguarding proprietary information, including requiring all employees who obtain access to proprietary information (under the terms of a protective order granted their employer) to sign and date a copy of that protective order.

* * * * *

(4) Failure to destroy and certify to the Department the destruction of all copies of the original documents and all notes, memoranda, and submissions containing proprietary information at the close of the proceeding for which the data were obtained by burning or shredding of the documents or by erasing electronic memory, computer disk, or tape memory, as set forth in the protective order.

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■ 14. In § 356.18, revise paragraph (c)(4) to read as follows:

§ 356.18 Interim sanctions.

* * * * *

(c) * * *

(4) Requiring the person to destroy and certify to the Department the destruction of all material previously provided by the Department or the investigating authority of the involved FTA country, and all other materials containing the proprietary information, such as briefs, notes, or charts based on any such information received under a protective order or disclosure undertaking.

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■ 15. In § 356.27, revise the paragraph (d) subject heading to read as follows:

§ 356.27 Final decision.

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(d) *Contents of final decision.* * * *

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[FR Doc. 2021-26551 Filed 12-8-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA-2019-N-3065]

RIN 0910-AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the Eastern District of Texas, this action delays the effective date of the final rule (“Tobacco Products; Required Warnings for Cigarette Packages and Advertisements”), which published on March 18, 2020. The new effective date is January 9, 2023.

DATES: The effective date of the rule amending 21 CFR part 1141 published at 85 FR 15638, March 18, 2020, and delayed at 85 FR 32293, May 29, 2020; 86 FR 3793, January 15, 2021; 86 FR 36509, July 12, 2021; and 86 FR 50854, September 13, 2021, is further delayed until January 9, 2023.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1371, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 18, 2020, the Food and Drug Administration (FDA or Agency) 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 label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 (Pub. L. 89-92)

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. 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 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 court granted a new motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.³ On March 2, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.⁴ On May 21, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.⁵ On August 18, 2021, the court issued an order to postpone the effective date of the final rule by an additional 90 days.⁶ On November 12, 2021, the court issued another order to postpone the effective date of the final rule by an additional 90 days.⁷ The court ordered that the new effective date of the final rule is January 9, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, the Agency’s implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exception in 5 U.S.C.

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. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

³ *R.J. Reynolds Tobacco Co.*, 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.*, 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.*, No. 6:20-cv-00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs’ motion and postponing effective date), Doc. No. 91.

⁶ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. August 18, 2021) (order postponing effective date), Doc. No. 92.

⁷ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. November 12, 2021) (order postponing effective date), Doc. No. 93.

553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 90-day postponement of the effective date, until January 9, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations.

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice: 11601]

RIN 1400-AF47

International Traffic in Arms Regulations: Addition of Cambodia to List of Proscribed Countries

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to add Cambodia in the list of countries for which it is the policy of the United States to deny licenses and other approvals for exports and imports of defense articles and defense services. This change reflects that it is the policy of the United States to deny all licenses and other approvals to export and import defense articles and defense services destined for or originating in Cambodia, except as otherwise provided herein.

DATES: The rule is effective on December 9, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Engda Wubneh, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663-1809, or email DDTCCustomerService@state.gov. ATTN: Regulatory Change, ITAR Section 126.1 Cambodia.

SUPPLEMENTARY INFORMATION: On June 1, 2021, the Department expressed serious concerns about the People's Republic of China's (PRC's) military presence and other activities in Cambodia and emphasized that a PRC military base in Cambodia would undermine Cambodian sovereignty, threaten regional security,

and negatively impact U.S.-Cambodia relations. Senior officials at the Departments of State and Defense continue to voice these concerns but Cambodia continues to allow the PRC to expand its military presence and construct exclusive-use facilities on the Gulf of Thailand.

In response to significant credible evidence of corruption, human rights abuses, and an exclusive agreement with the People's Republic of China (PRC) on military expansion in Cambodia by the Cambodian government, effective immediately, the Department is amending ITAR § 126.1 by adding Cambodia in paragraph (o) and revising the country policy chart in paragraph (d)(2). The policy of denial applies to licenses or other approvals for exports and imports of defense articles and defense services destined for or originating in Cambodia, with exceptions related to conventional weapons destruction and humanitarian demining activities. This action also precludes the use of exemptions from licensing or other approval requirements as described in that section.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a military or foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act (APA), pursuant to 5 U.S.C. 553(a)(1). Since this rule is exempt from 5 U.S.C 553, the provisions of section 553(d) do not apply to this rulemaking. Therefore, this rule is effective upon publication.

Regulatory Flexibility Act

Since this rule is exempt from the notice-and-comment provisions of 5 U.S.C. 553(b), there is no requirement for an analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This rulemaking will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, the Department has determined that this rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). Because the scope of this rule does not impose additional regulatory requirements or obligations, the Department believes costs associated with this rule will be minimal. This rule has not been designated a "significant regulatory action" by the Office and Information and Regulatory Affairs under Executive Order 12866.

Executive Order 12988

The Department of State has reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.