

**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 14, 2022.

**DATES:** The effective date of the rule amending 21 CFR part 1141 published at 85 FR 15638, March 18, 2020, is delayed until January 14, 2022.

**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: [AskCTPRregulations@fda.hhs.gov](mailto:AskCTPRregulations@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.<sup>1</sup> 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.<sup>2</sup> On December 2, 2020, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days.<sup>3</sup> The new effective date of the final rule is January 14, 2022. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of the final rule 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. 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 14, 2022, 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 issue and implementation of regulations.

Dated: January 6, 2021.

**Stephen M. Hahn,***Commissioner of Food and Drugs.*

Dated: January 8, 2021.

**Alex M. Azar II,***Secretary, Department of Health and Human Services.*

[FR Doc. 2021-00703 Filed 1-14-21; 8:45 am]

**BILLING CODE 4164-01-P****DEPARTMENT OF THE TREASURY****Office of Foreign Assets Control****31 CFR Part 585****Hong Kong-Related Sanctions Regulations****AGENCY:** Office of Foreign Assets Control, Treasury.**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is adding regulations to implement a July 14, 2020, Hong Kong-related Executive order. OFAC intends to supplement these regulations with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance, general licenses, and statements of licensing policy.

**DATES:** This rule is effective January 15, 2021.

**FOR FURTHER INFORMATION CONTACT:** OFAC: Assistant Director for Licensing, 202-622-2480; Assistant Director for Regulatory Affairs, 202-622-4855; or Assistant Director for Sanctions Compliance & Evaluation, 202-622-2490.

**SUPPLEMENTARY INFORMATION:****Electronic Availability**

This document and additional information concerning OFAC are available on OFAC’s website ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)).

**Background**

On July 14, 2020, the President, invoking the authority of, *inter alia*, the International Emergency Economic Powers Act (50 U.S.C. 1701-1706) (IEEPA), issued Executive Order (E.O.) 13936 of July 14, 2020, “The President’s Executive Order on Hong Kong Normalization” (85 FR 43413, July 17, 2020).

In E.O. 13936, the President determined that, pursuant to section 202 of the United States-Hong Kong Policy Act of 1992, the Special Administrative Region of Hong Kong (Hong Kong) is no longer sufficiently autonomous to justify differential treatment in relation to the People’s Republic of China (PRC or China) under the particular United States laws and provisions thereof set out in E.O. 13936. The President stated that in late May 2020, the National People’s Congress of China announced its intention to unilaterally and arbitrarily impose national security legislation on Hong Kong. He indicated that this announcement was China’s latest in a series of actions that have

<sup>1</sup> *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).

<sup>2</sup> *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

<sup>3</sup> *R.J. Reynolds Tobacco Co. et al.*, No. 6:20-cv-00176 (E.D. Tex. May 8, 2020) (order granting Plaintiffs’ motion and postponing effective date), Doc. No. 80.