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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-2020-N-1395]

RIN 0910-AI51

Prohibition of Sale of Tobacco Products to Persons Younger than 21 Years of Age

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is issuing a final rule to make conforming changes as required by the Further Consolidated Appropriations Act, 2020 (Appropriations Act), which established a new Federal minimum age of sale for tobacco products. These conforming changes include increasing the minimum age of sale for cigarettes, smokeless tobacco, and covered tobacco products from 18 to 21 years of age; increasing the minimum age for age verification by means of photographic identification for cigarettes, smokeless tobacco, and covered tobacco products from under the age of 27 to under the age of 30; increasing the minimum age of individuals who may be present or permitted to enter facilities that maintain vending machines to sell cigarettes, smokeless tobacco, or covered tobacco products from 18 to 21 years of age; and increasing the minimum age of individuals who may be present or permitted to enter facilities that maintain self-service displays that sell cigarettes or smokeless tobacco from 18 to 21 years of age.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this final rule 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.

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:

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I. Purpose of the Regulatory Action

The Appropriations Act, enacted on December 20, 2019, established and made immediately effective[1] a new Federal minimum age for the sale of tobacco products (Pub. L. 116-94, div. N, tit. I, subt. F, sec. 603, 133 Stat. 2534, 3123-24). Specifically, the Appropriations Act amended section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) (FD&C Act) to make it unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. The Appropriations Act also directed the Food and Drug Administration (FDA, the Agency, or we) to issue a final rule to amend its regulations to update the minimum age-related requirements in subpart B of part 1140 (21 CFR part 1140).

As required by the Appropriations Act, FDA is issuing this final rule to make conforming changes to its regulations to: (1) reflect the increased minimum age of sale for cigarettes[2], smokeless tobacco, and covered tobacco products from 18 to 21 years of age; (2) increase the minimum age for verification by means of photographic identification for cigarettes, smokeless tobacco, and covered tobacco products from under the age of 27 to under the age of 30; (3) increase the minimum age of persons who may be present or permitted to enter at any time for facilities that maintain vending machines to sell cigarettes, smokeless tobacco, or covered tobacco products from 18 to 21 years of age; and (4) increase the minimum age of persons who may be present or permitted to enter at any time for facilities that maintain self-service displays to sell cigarettes or smokeless tobacco from 18 to 21 years of age. This final rule ensures FDA's regulations align with current Federal law as it pertains to age restrictions and tobacco products, reducing youth access to such products and providing clarity to consumers, retailers, and manufacturers.

[1] Because the Appropriations Act did not provide a later effective date, the new provision became effective immediately.

[2] As discussed in section II.A of this document, unless otherwise stated, the restrictions in part 1140 that are applicable to cigarettes also apply to cigarette tobacco.

II. Background

FDA is amending part 1140 to apply the new Federal minimum age requirements for the sale of tobacco products to cigarettes, smokeless tobacco, and covered tobacco products.

A. The Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31, 123 Stat. 1776). In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products is a pediatric disease, virtually all new users of tobacco products are under 18 years of age, and that tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market (section 2(1), (4), (20), (23), (24) of the Tobacco Control Act) (21 U.S.C. 387 note). Accordingly, Congress directed FDA to reissue, among others, provisions contained in its 1996 final rule (61 FR 44396, August 28, 1996) that restricted youth access to tobacco products (section 102 of the Tobacco Control Act) (21 U.S.C. 387a-1).

Specifically, section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to FDA's 1996 final rule (61 FR 44396), with certain specified exceptions. Consistent with section 102 of the Tobacco Control Act, FDA published a final rule adding a new part 1140 to Title 21, that established restrictions on the sale and distribution of cigarettes and smokeless tobacco (75 FR 13225, March 19, 2010).

Among other things, the rule prohibited the sale of cigarettes and smokeless tobacco to any person younger than 18 years of age (§ 1140.14(a)); required retailers to verify by means of photographic identification that no person purchasing cigarettes or smokeless tobacco was

younger than 18 years of age (§ 1140.14(b)(1)), but did not require such verification for any person over the age of 26 (§ 1140.14(b)(2)); and prohibited the sale of cigarettes and smokeless tobacco through vending machines and self-service displays, except in facilities where individuals younger than 18 years of age were not present or permitted at any time (§ 1140.16(c)).

The final rule also set out definitions for "cigarette," "cigarette tobacco," and "smokeless tobacco" that mirrored those definitions set out at section 900 of the FD&C Act (21 U.S.C. 387). These terms were (and continue to be) defined in § 1140.3 as follows:

- *Cigarette* means a product that is a tobacco product; and meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.
- *Cigarette tobacco* means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.
- *Smokeless tobacco* means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

Products that meet these definitions are generally subject to the restrictions in part 1140.

B. The Deeming Rule and Covered Tobacco Products

On May 10, 2016, FDA issued a final rule deeming all products meeting the statutory definition of "tobacco product," excluding accessories of newly deemed tobacco products, to be subject to chapter IX of the FD&C Act and its implementing regulations (Deeming Rule) (81 FR

28974; codified at 21 CFR part 1100). Under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), the Deeming Rule also established age and identification restrictions for "covered tobacco products," defined as any tobacco product deemed to be subject to the FD&C Act under § 1100.2 (21 CFR 1100.2), but excluding any component or part that is not made or derived from tobacco (81 FR 28974 at 29103, codified at 21 CFR 1140.3).[3] Specifically, the Deeming Rule amended § 1140.14 to add, among others, provisions prohibiting retailers from selling covered tobacco products to any person younger than 18 years of age, requiring age verification by means of photographic identification for any person purchasing covered tobacco products under the age of 27, and prohibiting vending machine sales of covered tobacco products in facilities where persons younger than 18 years of age were present or permitted to enter at any time.

C. Further Consolidated Appropriations Act, 2020

Section 603(a) of the Appropriations Act amended chapter IX of the FD&C Act and established a new Federal minimum age of 21 years for the sale of tobacco products. Specifically, section 603(a) of the Appropriations Act added a new provision, that became effective immediately, to section 906(d) of the FD&C Act to make it unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age.[4]

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[3] The following is a nonexhaustive list of covered tobacco products subject to the minimum age and identification restrictions described in the Deeming Rule and this final rule: cigars, liquid nicotine, e-liquids and e-cigarettes containing nicotine, hookah/waterpipe tobacco, and pipe tobacco. In contrast, the following is a nonexhaustive list of components, parts, and accessories that do not meet the definition of a covered tobacco product and therefore are not subject to such restrictions: atomizers, batteries, waterpipe hose cooling attachments, flavored waterpipe charcoals, waterpipe tongs, lanyards, matches, and lighters. For more information, please visit the FDA website at https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products.

[4] Separately, the Consolidated Appropriations Act, 2022 (Pub. L. 117-103, 136 Stat. 49) was enacted on March 15, 2022. Among other things, the Consolidated Appropriations Act amended the definition of "tobacco product" in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) to include products that contain nicotine from any source (Pub. L. 117-103, div. P, tit. I, subt. B, sec. 111(a), 136 Stat. at 789). This amendment took effect on April 14, 2022 (*id.*, sec. 111(c), 136 Stat. at 789). As a result, it is unlawful for any retailer to sell a tobacco product containing nicotine from any source, including a non-tobacco nicotine product, to any person younger than 21 years of age.

While section 603(a) of the Appropriations Act refers to tobacco products in general, section 603(b) does not. As a result, this rule does not expand the scope of the products subject to the age-related restrictions, and instead simply increases the age thresholds for those restrictions. Section 603(b) of the Appropriations Act directed FDA to issue "a final rule to update the regulations issued under chapter IX of the [FD&C] Act (21 U.S.C. 387 *et seq*.) as appropriate" to (and only to) "carry out the amendments made by subsection (a)." The provision specified that such updates included updating all references to persons younger than 18 years of age in part 1140, subpart B and updating the relevant age verification requirements in part 1140 to require age verification for individuals under the age of 30. Thus, the regulations Congress directed FDA to update are the minimum age of sale restrictions in part 1140, subpart B and the related age verification restrictions in part 1140, all of which solely apply to cigarettes, smokeless tobacco, and covered tobacco products. FDA understands section 603(b) to direct FDA only to increase these age restrictions and not simultaneously to extend part 1140's age restrictions to apply to additional tobacco products. Section 603(b) identified two specific conforming changes; both called upon FDA to modify particular age restrictions within part 1140 — age restrictions that, as noted, apply only to cigarettes, smokeless tobacco, and covered tobacco products. In contrast to section 603(a) of the Appropriations Act, section 603(b) did not use the term "tobacco product," and neither of the age-related conforming changes identified in section 603(b) suggested that Congress expected FDA to apply the identified restrictions to *all* tobacco products. The legislative history of the Appropriations Act does not address section 603, and thus does not support a different conclusion. As such, this rule makes corresponding amendments to the relevant age restrictions in part 1140 but does not expand the range of products subject to such restrictions.

III. Legal Authority

Section 603 of the Appropriations Act amends section 906(d) of the FD&C Act to make it unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. Section 603 directs the Secretary to issue a final rule to update the regulations issued under chapter IX of the FD&C Act, including updating all references to persons younger than 18 years of age in part 1140, subpart B and updating relevant age verification requirements under part 1140 to require age verification for individuals under the age of 30. Under section 603(b)(1)(B), this final rule is deemed to be in compliance with all applicable provisions of chapter 5 of title 5, U.S. Code and all other provisions of law relating to rulemaking procedures. A proposed rule under 5 U.S.C. 553(b) is therefore neither required nor necessary.

IV. Description of the Final Rule

Consistent with the requirements of section 603 of the Appropriations Act, this rule updates part 1140 to: (1) increase the minimum age of sale for cigarettes, smokeless tobacco, and covered tobacco products from 18 to 21 years of age; (2) increase the minimum age for verification by means of photographic identification for cigarettes, smokeless tobacco, and covered tobacco products from under the age of 27 to under the age of 30; (3) increase the minimum age of persons who may be present or permitted to enter at any time for facilities that maintain vending machines to sell cigarettes, smokeless tobacco, or covered tobacco products from 18 to 21 years of age; and (4) increase the minimum age of persons who may be present or permitted to enter at any time for facilities that maintain self-service displays to sell cigarettes or smokeless tobacco from 18 to 21 years of age.

Specifically, in this final rule, FDA is revising the regulations as follows:

- In the heading to subpart B, by replacing the number “18” with the number “21”;

- In § 1140.14(a)(1), (a)(2)(i), (b)(1), (b)(2)(i), and (b)(3), by replacing the number "18" with the number "21";
- In § 1140.14(a)(2)(ii) and (b)(2)(ii), by replacing the number "26" with the number "29"; and
- In § 1140.16(c)(2)(ii), by replacing the number "18" with the number "21".

V. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order (E.O.) 12866, E.O. 13563, E.O. 14094, which direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are "significant" under E.O. 12866 section 3(f)(1) (as amended by E.O. 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this final rule is a significant regulatory action under E.O. 12866.

As directed by the Further Consolidated Appropriations Act, 2020, this final rule issued under section 603(b)(1)(B) is "deemed to be in compliance with all applicable provisions of chapter 5 of title 5, United States Code and all other provisions of law relating to rulemaking procedures." This exempts this rulemaking from such provisions of law as the Unfunded

Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq*., Pub. L. 104-4), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and Regulatory Flexibility Act (5 U.S.C. 601-612).

B. Benefits, Costs, and Transfers

In cases where the relevant statutory provisions are entirely self-implementing even in the absence of the regulation, or the regulatory action is one "over which an agency clearly has essentially no regulatory discretion", OMB's Circular A-4 allows for the use of a "with-statute" baseline. A with-statute baseline means that an Agency is only tasked to assess the impacts of the rule that are up to its discretion. Section 603(b) of the Appropriation Act charges FDA with publishing "in the Federal Register a final rule to update the regulations issued under chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387 et seq.)" to make edits to conform the regulations to the statutory changes. As FDA "clearly has essentially no regulatory discretion" over any of the provisions of this rule, we do not assess costs, benefits, or transfers for this final rule.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have federalism

implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

VIII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in E.O. 13175. FDA received a request for tribal consultation, but the Agency did not consider consultation on this regulation to be practicable. As previously discussed, the Appropriations Act established and made immediately effective a new Federal minimum age of 21 for the sale of tobacco products. The Appropriations Act also directed FDA to issue this final rule to make conforming changes to its regulations. Accordingly, a tribal summary impact statement is not required.

List of Subjects in 21 CFR Part 1140

Advertising, Labeling, Smoking, Tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1140 is revised as follows:

PART 1140--CIGARETTES, SMOKELESS TOBACCO, AND COVERED TOBACCO PRODUCTS

1. The authority citation for part 1140 is revised to read as follows:

Authority: 21 U.S.C. 301 *et seq.*; 21 U.S.C. 387a-1; Pub. L. 116-94, div. N, tit. I, subt. F, sec. 603, 133 Stat. 2534, 3123; Pub. L. 117-103, div. P, tit. I, subt. B, sec. 111(a), 136 Stat. 49, 789.

Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 21 Years of Age

2. Revise the heading for Subpart B to read as set forth above.

§ 1140.14 [Amended]

3. Amend § 1140.14 by:

a. Removing the number “18” and adding in its place the number “21” in paragraphs (a)(1), (a)(2)(i), (b)(1), (b)(2)(i), and (b)(3); and

b. Removing the number “26” and adding in its place the number “29” in paragraphs (a)(2)(ii) and (b)(2)(ii).

§ 1140.16 [Amended]

4. In § 1140.16(c)(2)(ii), remove the number “18” and add in its place the number “21”.

Dated: _____.

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