

Tobacco Retailer Training Programs (Revised) *

Guidance for Industry

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Tobacco Retailer Training Programs

Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document is intended to assist retailers in implementing training programs for employees to learn about and comply with the Federal laws, including regulations, regarding:

- Sale and distribution of, including youth access to, tobacco products
- Advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) does not require retailers to implement retailer training programs. However, the statute does provide for lower civil money penalties for violations of access, sale, and distribution restrictions, advertising and promotion restrictions, and required warning statements promulgated under section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to promulgate regulations establishing standards for approved retailer training programs. In the interim, however, for retailers who wish to implement training programs, this guidance document explains:

- Recommendations for elements to be included in a retailer training program
- Recommended hiring and management practices

¹ This guidance was prepared by the Office of Compliance and Enforcement and the Office of Regulations in the Center for Tobacco Products at FDA.

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- The civil money penalties that may be assessed against retailers for violations of restrictions promulgated under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act
- How the penalty structure differs for retailers with and without approved training programs

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Tobacco Control Act grants FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 906(d) of the FD&C Act, as amended by the Tobacco Control Act, states that “[t]he Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health.”

Section 102 of the Tobacco Control Act required FDA to publish final regulations regarding cigarettes and smokeless tobacco which are identical in their provisions to the regulations promulgated by FDA in 1996 (Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (1996 final regulations)),² with certain specified exceptions. The regulation (codified at 21 CFR part 1140) is deemed to be issued under chapter IX of the FD&C Act, as amended by the Tobacco Control Act. The regulation contains provisions designed to limit young people's access to cigarettes and smokeless tobacco products, as well as restrictions on advertising and promotion of cigarettes and smokeless tobacco products, to curb the appeal of these products to minors (75 FR 13225; March 19, 2010).

On August 8, 2016, FDA's final regulations entitled “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products”³ (the Deeming Rule) became effective and expanded FDA's tobacco product authority to include all products meeting the statutory definition of a tobacco product, except for accessories of newly deemed tobacco products. As a result of the Deeming Rule, some restrictions in parts 1140 now apply to covered tobacco

² See 61 FR 44396 (Aug. 28, 1996).

³ 81 FR 28974 (May. 10, 2016).

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products in addition to cigarettes and smokeless tobacco. Additionally, the Deeming Rule added 21 CFR part 1143, which contains requirements for required warning statements for cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products.

A. Provisions Regarding Sale and Distribution

The regulations impose, among other things, the following restrictions on sale and distribution of, including youth access to, tobacco products.⁴

Retailers of tobacco products MUST:

1. Not sell cigarettes, smokeless tobacco, or covered tobacco products to persons younger than 18 years of age (21 CFR 1140.14(a)(1) and (b)(1)).
2. Verify the age of purchasers of cigarettes, smokeless tobacco, and covered tobacco products who are under the age of 27 by means of photographic identification that contains the bearer's date of birth (21 CFR 1140.14(a)(2) and (b)(2)).
3. Only sell cigarettes or smokeless tobacco in direct, face-to-face transactions, with limited exceptions (21 CFR 1140.14(a)(3) and 1140.16(c)).
4. Not sell cigarettes and smokeless tobacco using vending machines or self-service displays unless they are located in a facility where the retailer ensures that persons younger than 18 years of age are not present or permitted to enter at any time (21 CFR 1140.14(a)(3) and 1140.16(c)).
5. Not sell covered tobacco products using vending machines unless they are located in a facility where the retailer ensures that persons younger than 18 years of age are not present at any time (21 CFR 1140.14(b)(3)).
6. Remove or bring into compliance all self-service displays, advertising, labeling and other items located in the retailer's establishment that do not comply with the requirements under 21 CFR 1140 (21 CFR 1140.14(a)(5)).
7. Not break or otherwise open packages of cigarettes to sell or distribute single cigarettes or sell any package with less than 20 cigarettes (21 CFR 1140.14(a)(4), 21 CFR 1140.16(b)).
8. Not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual use (21 CFR 1140.14(a)(4)).
9. Not distribute free samples of tobacco products, except for samples of smokeless tobacco products in a qualified adult-only facility, as defined by the regulations (21 CFR 1140.16(d)).

⁴ For the full text of the regulation, refer to 21 CFR parts 1140 and 1143.

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Additionally, certain requirements went into effect on May 10, 2018. For these requirements, FDA has provided a compliance date of August 10, 2018.⁵ On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted. Under these requirements retailers of tobacco products MUST:⁶

10. Not sell or offer to sell cigarette tobacco, roll-your-own tobacco, or covered tobacco products other than cigars unless the product package bears the required warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." (21 CFR 1143.3(a)).⁷
11. Not sell or offer to sell a cigar product (other than cigars sold individually and not in the product package) unless the product package bears one of the warning statements in 21 CFR 1143.5(a)(1) on the package label. (21 CFR 1143.5(a)(1)).
12. Not sell or offer to sell cigars individually and not in the product package, unless the required warning statements in 21 CFR 1143.5(a)(1) are posted at the retailer's point-of-sale as described in 21 CFR 1143.5(a)(3). (21 CFR 1143.5(a)(3)).

B. Provisions Regarding Advertising and Promotion

The regulations impose, among other things, the following restrictions on advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products.⁸ Retailers of tobacco products MUST:

1. Notify the Agency 30 days prior to the use of advertising or labeling for cigarettes or smokeless tobacco which the retailer intends to disseminate or cause to be disseminated

⁵ See FDA's guidance for industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Nov. 2017), available at:

<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm557714.htm>.

⁶ For the three requirements listed above (numbers 10-12), retailers may continue to sell and distribute tobacco products with packaging that does not bear the required health warning statements after the effective date, but only if the products were manufactured before the effective date of the warning statement requirements. See 21 CFR 1143.13(a). For more information on compliance dates, see FDA's guidance for industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (August, 2018), available at:

<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm557714.htm>.

⁷ The nicotine addictiveness warning statement is not required for products that do not contain nicotine if the tobacco product manufacturer has submitted to FDA a confirmation statement certifying to be true and accurate that the product does not contain nicotine and that the tobacco product manufacturer has data to support that assertion. However, such products must include a statement: "This product is made from tobacco." (21 CFR 1143.3(c)).

⁸ On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found 21 CFR 1140.32(a) and 21 CFR 1140.34(b) to be unconstitutional under the First Amendment. (See *Discount Tobacco, et al v. United States*, 674 F.3d 509 (6th Cir. 2012).) Therefore, FDA will not seek to enforce these provisions.

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in a medium that is not listed in 21 CFR 1140.30(a)(1). The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The retailer shall send this notice to the U.S. Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, Attn: Office of Compliance and Enforcement, 10903 New Hampshire Avenue, Silver Spring, MD 20993 (21 CFR 1140.30(a)(2)).

2. Not sponsor, or cause to be sponsored, any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco (21 CFR 1140.34(c)).

Additionally, certain requirements went into effect on May 10, 2018. For these requirements, FDA has provided a compliance date of August 10, 2018.⁹ On July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted. Under these requirements retailers of tobacco products **MUST**:

1. Not advertise or cause to be advertised any cigarette tobacco, roll-your-own tobacco, or covered tobacco products other than cigars unless each advertisement bears the required warning statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." (21 CFR 1143.3(b)).¹⁰
2. Not advertise or cause to be advertised any cigar unless each advertisement bears one of the required warning statements specified in 21 CFR 1143.5(a)(1). (21 CFR 1143.5(b)).

C. Required Warning Statements

As described in sections II.A. and B. above, the regulations impose, among other things, warning statement requirements for the sale, offer for sale, and advertising of cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products.¹¹

For cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars, the package or advertising must contain the statement "WARNING: This product contains nicotine. Nicotine is an addictive chemical." (21 CFR 1143.3(a)(1) and 1143.3(b)) and meet the format requirements of 21 CFR 1143.3(a)(2) and (b)(2), respectively. As stated above, on July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning

⁹ See footnote five, *supra*.

¹⁰ See footnote six, *supra*.

¹¹ This guidance applies only to warning statement requirements promulgated under FD&C Act section 906(d), which are subject to the penalty schedules prescribed by section 103(q)(2) of the Tobacco Control Act, described *infra*.

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requirements for cigars and pipe tobacco (21 CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.

For cigar products, the package or advertising must contain one of the warning statements required by 21 CFR 1143.5(a)(1) and meet the format requirements of 1143.5(a)(2) and (b)(2), respectively. For cigars sold individually and not in the product package, the required warning statements in 21 CFR 1143.5(a)(1) must be posted at the retailer's point-of-sale and meet format requirements, as described in 21 CFR 1143.5(a)(3). As stated above, on July 5, 2018, the U.S. District Court for the District of Columbia enjoined FDA from enforcing the warning requirements for cigars and pipe tobacco (21 CFR 1143.3 and 1143.5) until 60 days after the final disposition of the plaintiffs' appeal in the case: *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal); *see also Cigar Ass'n of America v. FDA*, No. 18-5195 (D.C. Cir.). FDA will not seek to enforce the warning requirements for cigars and pipe tobacco until that order is lifted.

It is important to note that retailers of cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products will not be found in violation of the warning statement requirements for packaging that:

- Contains a health warning.
- Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor, who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable.
- Is not altered by the retailer in a way that is material to the requirements of sections 1143.3(a) and 1143.5(a).
(21 CFR 1143.3(a)(3) and 1143.5(a)(4))

Additionally, the warning statement requirement for advertisements outlined in sections 1143.3(b) and 1143.5(b) apply to a retailer only if that retailer is responsible for or directs the health warning required under the paragraph. However, this does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that:

- Does not contain a health warning
- Contains a health warning that has been altered by the retailer in a way that is material to the requirements of sections 1143.3(b) and 1143.5(b)
(21 CFR 1143.3(b)(3) and 1143.5(b)(3))

D. Civil Money Penalties

Section 103(q)(2) of the Tobacco Control Act includes two schedules for assessing civil money penalties against retailers for violations of restrictions promulgated under section 906(d) of the

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FD&C Act, as amended by the Tobacco Control Act.¹² Under each schedule, violators are subject to increasing penalties for subsequent violations within prescribed time periods.

Specifically, section 103(q)(2)(A) sets forth the civil money penalty structure as follows:¹³

- (i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed –
 - (I) in the case of the first violation, \$0.00 together with the issuance of a warning letter to the retailer;¹⁴
 - (II) in the case of a second violation within a 12-month period, \$250;
 - (III) in the case of a third violation within a 24-month period, \$500;
 - (IV) in the case of a fourth violation within a 24-month period, \$2,000;
 - (V) in the case of a fifth violation within a 36-month period, \$5,000; and
 - (VI) in the case of a sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.
- (ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed –
 - (I) in the case of the first violation, \$250;
 - (II) in the case of a second violation within a 12-month period, \$500;
 - (III) in the case of a third violation within a 24-month period, \$1,000;
 - (IV) in the case of a fourth violation within a 24-month period, \$2,000;
 - (V) in the case of a fifth violation within a 36-month period, \$5,000; and

¹² Section 303(f)(9) of the FD&C Act establishes civil money penalties for violations of tobacco product requirements under the FD&C Act. This guidance only applies to civil money penalties for retailer violations of regulations issued under section 906(d) of the FD&C Act; it does not apply to civil money penalties issued under section 303(f)(9) for other violations.

¹³ The Civil Money Penalty amounts listed in this guidance reflect the amounts listed in the statute. FDA is required to update these amounts annually to reflect inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74 (2015), codified at 28 U.S.C. 2461 note 2(a)). For the most up-to-date amounts, please see 45 CFR 102.3 or the CTP website at: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm>

¹⁴ Although the penalty for the first violation is \$0.00, consistent with the statute CTP will issue a Warning Letter.

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(VI) in the case of a sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.

For the first three violations in a 24-month period, retailers with an approved training program are subject to lower maximum penalties than retailers without such programs. Section 103(q)(2)(B) of the Tobacco Control Act defines “approved training program” as a training program that complies with standards developed by the FDA for such programs.

FDA intends to promulgate regulations establishing standards for approved retailer training programs. Until it does, the Agency intends to seek penalties in accordance with the section for retailers with an approved training program (section 103(q)(2)(A)(i) of the Tobacco Control Act), whether or not the retailer has implemented a training program. However, FDA may consider any evidence of a training program (e.g., training curriculum, a test provided to employees and their test scores) in determining whether to further reduce the civil money penalty during settlement negotiations for retailers who violate the regulations.¹⁵

E. No-Tobacco-Sale Orders

In addition to civil money penalties, the statute allows the Secretary to impose no-tobacco-sale orders on retailers who repeatedly violate restrictions promulgated under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act. Specifically, section 103(c) of the Tobacco Control Act amends section 303(f) of the FD&C Act (21 U.S.C. 333(f)) to add the following:

“If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty”

III. GENERAL INFORMATION

A. What definitions apply?

The following definitions apply for purposes of this guidance:

1. *Cigarette*: The term ‘cigarette’ (a) 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 (b) 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 (section 900(3) of the FD&C Act; 21 U.S.C. 387(3)). This definition refers to a provision of the Federal Cigarette Labeling and Advertising Act

¹⁵ For additional information, see “Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers,” available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>.

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which defines the term ‘cigarette’ as:

“(1) The term “cigarette” means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and
(B) any roll of tobacco wrapped in any substance containing tobacco 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 described in subparagraph (A)” (15 U.S.C. 1332).

2. *Cigarette Tobacco*: The term ‘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 chapter IX of the FD&C Act shall also apply to cigarette tobacco (section 900(4) of the FD&C Act (21 U.S.C. 387(4)).
3. *Component or part*: The term component or part¹⁶ means any software or assembly of materials intended or reasonably expected:
 - (1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or
 - (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory¹⁷ of a tobacco product (21 CFR 1140.3 and 1143.1).
4. *Covered tobacco product*: The term ‘covered tobacco product’ means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act by 21 CFR § 1100.2, but excludes any component or part that is not made or derived from tobacco (21 CFR 1140.3 and 1143.1).
5. *Package or packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers (21 CFR 1143.1).
6. *Point-of-sale* means any location at which a consumer can purchase or otherwise obtain tobacco products for personal consumption (21 CFR 1143.1).
7. *Required warning statement* means a textual warning statement required to be on packaging and in advertisements for cigarette tobacco, roll-your-own tobacco, cigars, and other covered tobacco products (21 CFR 1143.1).
8. *Smokeless Tobacco*: The term ‘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 (section 900(18) of the FD&C Act; 21 U.S.C. 387(18)).
9. *Retailer*: The term ‘retailer’ means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-

¹⁶ FDA notes that component and part are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of 21 CFR part 1140 and this guidance, FDA is using the terms component and part interchangeably and without emphasizing the distinction. FDA may clarify the distinctions between component and part in the future.

¹⁷ The term “accessory” means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product (21 CFR 1140.3 and 1143.1).

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service displays of tobacco products are permitted (section 900(14) of the FD&C Act; 21 U.S.C. 387(14)).

B. What products are covered by this guidance?

The regulations in 21 CFR part 1140 apply to cigarettes, cigarette tobacco, smokeless tobacco, and covered tobacco products (e.g., cigars, pipe tobacco, e-cigarettes, e-liquids that contain nicotine). The regulations in 21 CFR part 1143 apply to cigarette tobacco, roll-your-own tobacco, and covered tobacco products.

IV. RETAILER TRAINING PROGRAMS

A retailer training program should provide the information and tools necessary for employees to comply with the Federal laws, including regulations, restricting the sale and distribution, including youth access, and the advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products.¹⁸ FDA believes that the elements described in this guidance are important components of an effective retailer training program based on the best available evidence to date.

Some retailers may already have a training program in place for other purposes (e.g., company policy, State or local law). FDA recommends that retailers who want to train employees about Federal requirements incorporate the elements described in this guidance into their existing training program, as appropriate.

As soon as practicable, current employees should receive comprehensive training on the Federal laws, including regulations, restricting the sale and distribution, including youth access, and the advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products.¹⁹ New employees should receive the training prior to selling cigarettes, smokeless tobacco, or covered tobacco products.

A. What are the recommended elements to be included in a retailer training program?

The training should include detailed information on the Federal laws, including regulations, concerning the sale and distribution, including youth access, and the advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products. Training content should include information on all of the following:

1. Applicable Laws and Penalties

¹⁸ See section II of this guidance.

¹⁹ FDA notes that there may be additional, and possibly stricter, State and local laws relating to the sale and distribution of, access to, and advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products. Retailers should consult with State and local authorities for further information.

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Training content should describe Federal laws, including regulations, restricting the sale and distribution, including youth access, and the advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products. These laws, including regulations, are briefly summarized in section II of this guidance. Training content also should discuss the penalties for violations of these laws.

2. Health Effects of Youth Tobacco Use

Training program content should include a description of the health and economic effects of tobacco use, especially when tobacco use begins at a young age. FDA recommends that retailers describe the negative health effects of youth tobacco use. For example, the Congressional Findings in the Tobacco Control Act, Surgeon General's Reports, and other authoritative scientific studies have reported the following:

- Tobacco use is the foremost preventable cause of premature death in America. It causes over 480,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.^{20, 21}
- Smoking costs the United States \$193 billion every year from health care costs and lost productivity from premature death. The actual costs are even higher because lost productivity from illness is not included in this estimate.²²
- Cigarette smoking harms nearly every organ in the body. Smoking is known to cause many serious diseases, including multiple cancers (lung, kidney, bladder, acute myeloid leukemia, mouth and throat, larynx, esophagus, stomach, pancreas, cervix); chronic lung disease; heart attacks; stroke; aortic aneurysm; pneumonia; reduced lung function in infants, adolescents, and adults; respiratory symptoms in children and adolescents; asthma-related symptoms; reduced fertility in women; pregnancy complications including premature birth, low birth weight; sudden infant death syndrome (SIDS); peptic ulcer disease; adverse surgical outcomes; osteoporosis and hip fractures in women; periodontal disease; and cataracts. There are also studies linking many other diseases to cigarettes.²³
- Smokeless tobacco causes oral cancer, esophageal cancer, and pancreatic cancer. Using smokeless tobacco may also cause heart disease, gum disease, oral lesions

²⁰ Section 2(13) of the Tobacco Control Act.

²¹ Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, *The Health Consequences of Smoking -- 50 Years of Progress: a Report of the Surgeon General* 659, 2014.

²² Centers for Disease Control and Prevention, "Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004," *Morbidity and Mortality Weekly Report*, 57(45); 1226-28, Nov. 14, 2008, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>.

²³ U.S. Department of Health and Human Services, "The Health Consequences of Smoking," A Report of the Surgeon General; 2004, available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

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other than cancer, reduced sperm count, and pregnancy complications including premature birth and low birth weight.²⁴

- The adverse health impact of smoking is not limited to adults. Smoking among children and adolescents causes their lungs to not fully develop and causes a premature and accelerated decline in lung function beginning in early adulthood. Smoking also causes respiratory symptoms and asthma-related symptoms in children and adolescents.²⁵
- Cigarettes, smokeless tobacco, and covered tobacco products contain nicotine, an addictive chemical.²⁶
- Data suggest that youth are particularly susceptible to becoming addicted to tobacco.²⁷
- Virtually all new users of tobacco products are under the minimum legal age to purchase such products.²⁸

Retailers also should inform employees that one way to prevent the significant adverse consequences of tobacco use is to prevent youth from purchasing cigarettes, smokeless tobacco, and covered tobacco products.

A retailer may choose to use other examples and/or statistics in its training program than what is recommended above; however, the training program should incorporate specific examples and/or statistics related to the health effects of youth tobacco use.

3. Written Company Policies

Retailers should adopt and enforce a written policy covering Federal laws, including regulations, related to the sale and distribution, including youth access, and the advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products.²⁹ This policy should be shared with all employees both verbally and in writing, acknowledged by the employees, and documented in their training records.

4. Comprehensive Description of Tobacco Products Covered by Laws Prohibiting the Sale of Tobacco Products to Youth

²⁴ World Health Organization. "Smokeless Tobacco and Some Tobacco-specific *N*-Nitrosamines." International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 89; 2007, available at <http://monographs.iarc.fr/ENG/Monographs/vol89/mono89.pdf>.

²⁵ U.S. Department of Health and Human Services, "The Health Consequences of Smoking," A Report of the Surgeon General; 2004, available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/complete_report/index.htm.

²⁶ U.S. Department of Health and Human Services, "The Health Consequences of Smoking: Nicotine Addiction," A Report of the Surgeon General; 1988.

²⁷ U.S. Department of Health and Human Services, "How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease," A Report of the Surgeon General; 2010, available at http://www.surgeongeneral.gov/library/tobaccosmoke/report/full_report.pdf.

²⁸ Section 2(4) of the Tobacco Control Act.

²⁹ See section II of this guidance.

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The training curriculum should clearly define which products sold in the retail establishment are considered to be cigarettes, smokeless tobacco, and covered tobacco products under the Tobacco Control Act and are therefore subject to the Federal regulations prohibiting their sale to individuals under the age of 18.

5. *Age Verification Techniques*

Program content should clearly describe both Federal law and company policies on requiring identification, including the age that triggers photographic identification verification and what constitutes acceptable forms of identification.

- ***Photographic Identification Containing Date of Birth Requirements.*** Unless otherwise required by law, FDA recommends that retailers have in place a policy that:
 - Permits only government-issued photographic identification containing a *date of birth* (e.g., State-issued driver's license or identification card, military identification card, passport, or immigration card) as acceptable forms of identification for establishing a legal age to purchase cigarettes, smokeless tobacco, and covered tobacco products.
 - Specifies that the photographic identification cannot be expired.
 - Includes appropriate measures to determine the authenticity of the government-issued photographic identification (as further described below).
 - Instructs employees to decline a sale when the customer has no photographic identification, the photographic identification contains no date of birth, or the photographic identification has expired.
- ***The Importance of Closely Examining Photographic Identification.*** The training curriculum should teach retail personnel about the need to closely examine photographic identification to ensure that it establishes both that the person identified is of legal age to purchase cigarettes, smokeless tobacco, and covered tobacco products and that the identification belongs to the person who is presenting it. The training curriculum also should instruct employees to decline a sale because of concerns about the authenticity of the photographic identification. This portion of the training should stress that many illegal sales are made to minors who produce identifications showing that they are under the legal age to purchase cigarettes, smokeless tobacco, and covered tobacco products. Specifically, studies have shown that illegal sales to minors frequently occur when a retail employee fails to verify the age of the purchaser who has produced the identification, especially when the minor appears to be confident, produces a

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photographic identification without being asked, and appears to be over the age of 18.^{30, 31}

- ***How to Verify the Authenticity of Photographic Identification.*** Program content should include information on the features of a photographic identification that should be checked. These could include, but are not limited to:
 - Close examination of the picture and physical characteristics listed on the identification (such as height, weight, and eye color) to ensure that the identification belongs to the person who has presented it.
 - Examination of the identification to ensure any required watermarks or State seals are present.
 - Examination of the identification for visual clues to assist in determining whether it belongs to an of age or underage customer in States where photographic identification has different features for individuals under age 21 or under age 18 (such as vertical versus horizontal orientation or different font color on the date of birth).

- ***Altered Photographic Identification.*** Training also should discuss how to determine whether a photographic identification might have been altered and what an employee should do if a photographic identification appears to be altered. Specifically, the training program should provide detailed information on signs of an altered photographic identification, which include, but are not limited to:
 - Any sign of tampering
 - Peeling lamination
 - Smudged print
 - Differences in font on the date of birth or expiration date

- ***Specific Age-Verifying Techniques.*** Training content should include detailed information on company-approved techniques designed to ensure that the date of birth on photographic identification is read and clearly understood. For example, retailers may choose to implement one or more of the following techniques to assist employees in calculating a purchaser's age:
 - Requiring employees to compare the date of birth on the photographic identification with a calendar that displays the most recent date that can be shown on the photographic identification in order for that person to purchase cigarettes, smokeless tobacco, and covered tobacco products.
 - Installing price scanners that are programmed so that when a tobacco product is scanned, the register displays a message prompting the

³⁰ Pearson, D., *et al.*, "Youth tobacco sales in a metropolitan county: factors associated with compliance," *American Journal of Preventive Medicine*, 33(2); 91-97, 2007.

³¹ Klonoff, E., and Landrine, H., "Predicting Youth Access to Tobacco: The Role of Youth Versus Store-Clerk Behavior and Issues of Ecological Validity," *Health Psychology*, 23(5); 517-24, 2004.

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employee either to request age identification and key in the purchaser's date of birth or to verify that the purchaser is over the age of 26.

- Requiring employees to scan all photographic identifications through an electronic age verification device.

- ***Insufficient Photographic Identification.*** Training also should inform employees of how and when they should ask for a second piece of photographic identification containing the purchaser's date of birth and instruct employees to decline a sale when the photographic identification does not appear to be authentic.

6. *Refusing Sales*

- ***Practical Guidance for Refusing Sales When Appropriate.*** FDA recommends that training programs incorporate role-playing (e.g., practice sessions with retail employees playing roles as clerks and customers to simulate possible sales transactions) to ensure that employees can effectively apply training information and perform the tasks outlined in the training program. Role-playing should address difficult situations and should assist employees in determining when and how to:
 - Decline purchase attempts by a minor made with written parental permission.
 - Decline to sell cigarettes, smokeless tobacco, and covered tobacco products to underage persons who are friends and acquaintances.
 - Decline a sale when the customer has no photographic identification, the photographic identification contains no date of birth, the photographic identification has expired, the photographic identification does not appear to be authentic, or the photographic identification shows the customer to be underage.
 - Resist customer pressure.
 - Seek management assistance, when necessary.

Other situations or issues should be included in role-playing exercises, as needed.

- ***The Right to Refuse Sales When Acting in Good Faith.*** The training curriculum should teach retail personnel that employees are not required to make a cigarette, smokeless tobacco, or covered tobacco product sale if there is any question that doing so would violate the law.

7. *Testing to Ensure That Employees Have the Knowledge Required*

Retailers should require employees to take a written test, using any content, format, and method determined by the retailer to be appropriate, that covers the Federal laws, including regulations, related to the sale and distribution, including youth access, and the

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advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products.³² Each employee should attain a score sufficient to demonstrate that he or she possesses the knowledge necessary to comply with the law. Retailers should maintain records documenting that all individual employees have been trained, including:

- One copy of the test given to employees and the correct answers.
- A record of the test results for each employee, including the employee's name, the date(s) of testing, the test given to the employee (if the retailer has more than one test for such training), and the employee's test score.³³

Retailers should determine the format of the records (e.g., paper, electronic) and should retain the records for 4 years in order to be able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

B. What are the recommendations for training frequency, methods, and review?

1. Frequency

Current employees should be trained as soon as practicable. New retail employees should be trained prior to selling cigarettes, smokeless tobacco, and covered tobacco products. All employees should receive refresher training, including, but not limited to, any necessary re-training, updates to company policies or the law, testing, and role-playing exercises. Refresher training should be provided at least yearly and more frequently as needed. For instance, retailers should consider requiring refresher training and testing for employees if a retail employee is found selling cigarettes, smokeless tobacco, or covered tobacco products to persons under the age of 18.

2. Methods

The training curriculum may be delivered by any appropriate method, including, but not limited to, in-store training while on the job, a trainer in a classroom setting, via written materials provided to store personnel for self-study, or via Web or other computer-based applications.

3. Training Program Review Following a Violation of the Regulations

FDA recommends that retailers review and update their training program, as needed, and take appropriate corrective action after any violation of the regulations restricting sale and distribution, including youth access, and advertising and promotion of cigarettes, smokeless tobacco, and covered tobacco products. Retailers should document any modifications to the training program following such a review and should retain the records for 4 years in order to be able to provide evidence of a training program during

³² See section II of this guidance.

³³ Retailers may determine how to document and retain this information (e.g., logbook, spreadsheet, database).

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the 48-month time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

C. What hiring and management practices support a retailer training program?

FDA recommends that appropriate retailer hiring and management practices be implemented as part of a retailer training program.

1. Hiring Practices

FDA recommends that retailers consider requiring employees who sell cigarettes, smokeless tobacco, and covered tobacco products to be at least 18 years of age.³⁴ Studies have shown that employees under the age of 18 are more likely to sell tobacco to minors than are older clerks.³⁵ Also, facilities that employ persons younger than 18 years of age must not have vending machines for the sale of cigarettes, smokeless tobacco, or covered tobacco products (21 CFR 1140.14(a)(3); 21 CFR 1140.14(b)(3); 21 CFR 1140.16(c)(1)), or self-service displays for the sale of cigarettes or smokeless tobacco (21 CFR 1140.16(c)(1)).

2. Management Practices

Retailers should consider implementing an internal compliance check program, also known as a mystery shopper program, taking into account any State or local laws related to such programs. Internal compliance checks should be performed at random and varying times of the day and at least once every 6 months. Employees who fail the internal compliance check should be notified immediately and given additional training.

Retailers who have in-store videotaping should periodically review the tapes to ensure that employees are complying with sales to minor laws and store policies related to reducing the illegal sale of cigarettes, smokeless tobacco, and covered tobacco products to underage youth. Specifically, retailers should review the tapes to ensure that store employees are requesting and examining photographic identification from customers who are under the age of 27.

Retailers should consider establishing company policies that take employee performance on compliance checks into account. In particular, retailers should consider establishing appropriate corrective measures, in accordance with State and local law, for employee noncompliance. FDA recommends that retailers document the procedures and corrective actions for their internal compliance check program. Such records should be retained for 4 years in order to be able to provide evidence of a training program during the 48-month

³⁴ FDA regulations do not establish a minimum age for employees who sell tobacco products, but some State or local laws may do so. FDA recommends that retailers contact State and local authorities for information about any age requirements.

³⁵ DiFranza, J.R., and Coleman, M., "Sources of tobacco for youths in communities with vigorous enforcement of tobacco sales laws," *Tobacco Control*, 10; 323-328, 2001.

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time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

To ensure that management has a vested interest in employee compliance with laws prohibiting the sale of cigarettes, smokeless tobacco, and covered tobacco products to underage youth, retailers also should consider making a store's compliance rate a component of a retail supervisor's performance reviews, if permitted by law.

V. HOW CIVIL MONEY PENALTIES WILL BE ASSESSED FOR VIOLATIONS OF REGULATIONS

The Tobacco Control Act does not require retailers to implement retailer training programs. However, it provides for two schedules of civil money penalties for violations of restrictions promulgated under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act, pertaining to the sale and distribution of tobacco products, including youth access, and advertising and promotion restrictions—a schedule of lower penalties for retailers who have implemented a training program that complies with the standards set by FDA and a schedule of higher penalties for those who have not.

Retailers are under no obligation to submit their training programs for FDA review because this is a voluntary program. Until FDA promulgates regulations establishing standards for approved retailer training programs, the Agency intends to seek penalties in accordance with section 103(q)(2)(A)(i) of the Tobacco Control Act (for retailers with an approved retailer training program), whether or not the retailer has implemented a training program. FDA may consider further reducing the civil money penalty for retailers who have implemented a training program.

Retailers who have received a Complaint for Civil Money Penalties or No-Tobacco-Sale Order and who wish to submit evidence that they have a training program in place, for purposes of settlement negotiations, may do so when filing an Answer to the Complaint. Retailers who have not received a Complaint should not submit their training programs for FDA review.

The Complaint for Civil Money Penalties or No-Tobacco-Sale Order and the accompanying cover letter will include detailed information on how to file an Answer and submit related documentation, including evidence that a retailer has a training program. Until FDA promulgates regulations establishing standards for approved retailer training programs, the Agency may consider any evidence of a training program (e.g., the training curriculum, the test provided to employees and their test scores) in determining whether to further reduce the civil money penalty for retailers who violate the regulations.³⁶

³⁶ For additional information, see “Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers,” available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>.

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VI. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 10 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0745 (expires 12/31/2019).

DOCUMENT HISTORY:

- September 2013 – Final guidance was issued.
- June 2014 – Pages 4-5 were updated with new Civil Money Penalty amounts that reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act; references to CTP’s address updated throughout the document.
- May 2018 – Throughout the document, edits were made to improve the clarity of the document and to reflect the provisions that apply to covered tobacco products under the Deeming Rule; Pages 2 and 3 were edited to discuss the Deeming Rule; Pages 6 and 7 were updated to reflect amendments to the Civil Money Penalty Inflation Adjustment Act and to include reference to the CTP website for current amounts; Pages 8 and 9 have been edited to include definitions for the terms “accessory,” “component or part,” and “covered tobacco product.”
- June 2018 – A footnote was added to page 4 to clarify that the effective date of the new health warning requirements for covered tobacco products, cigarette tobacco, and RYO tobacco is with respect to the date of manufacture.
- August 2018 – Section II of guidance is revised to reflect a stay of enforcement of the warning requirements for cigars and pipe tobacco (21 CFR §§ 1143.3 and 1143.5) after the United States District Court for the District of Columbia granted plaintiffs’ motion

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for an injunction pending appeal. *Cigar Ass'n of America v. FDA*, No. 1:16-cv-01460 (D.D.C.) (order granting injunction pending appeal).

– Clarifying and corrective edits made throughout the document.