

# Draft Guidance for Industry

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## Tobacco Retailer Training Programs

### *Draft Guidance*

**This guidance is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted by September 14, 2010, as described in the notice announcing the availability of the draft guidance in the *Federal Register*. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Tobacco Products (CTP) at 1-877-CTP-1373.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products**

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# **Draft Guidance for Industry<sup>1</sup>**

## **Tobacco Retailer Training Programs**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

### **I. Introduction**

This guidance document is intended to assist tobacco retailers in implementing effective training programs for employees to learn the Federal laws restricting the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, cigarettes and smokeless tobacco products. This document also provides retailers with guidance on implementing effective training on how to request and verify the photo identification of purchasers younger than 27 years of age and how to refuse the sale of cigarettes or smokeless tobacco to purchasers younger than 18 years of age.

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, advertising and promotion restrictions promulgated under section 906(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by the FDA for such programs. The 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:

- The civil money penalties that may be assessed against retailers for violations of restrictions promulgated under section 906(d) of the FFDCA, as amended by the Tobacco Control Act, pertaining to restrictions on the

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<sup>1</sup> This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.

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sale and distribution of a tobacco product, including access, promotion and advertising restrictions;

- How the penalty structure differs for retailers with and without approved training programs;
- Definitions;
- Recommendations for elements to be included in a retailer training program; and
- Recommended hiring and management practices.

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 guidelines means that something is suggested or recommended, but not required.

## **II. Background**

On June 22, 2009, the President signed the Tobacco Control Act into law. The Tobacco Control Act grants FDA important new 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 FFDCAs, 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 requires FDA to re-issue its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products. The regulation is deemed to be issued under Chapter 9 of the FFDCAs, as amended by the Tobacco Control Act. The regulation contains provisions designed to limit young people's access to cigarettes and smokeless products, as well as restrictions on advertising and promotion of such tobacco products, to curb the appeal of these products to minors (75 FR 13225; March 19, 2010).

Specifically, the regulation imposes the following restrictions:

### Restrictions on Access to Tobacco Products

Retailers of tobacco products MUST:

- Not sell cigarettes or smokeless tobacco to persons younger than 18 years of age (21 CFR 1140.14(a)).
- Verify the age of purchasers of cigarettes or smokeless tobacco who are under the age of 27 by means of photographic identification that contains the bearer's date of birth (21 CFR 1140.14(b)).

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### Restrictions on Sale and Distribution of Tobacco Products

Retailers of tobacco products MUST:

- Only sell cigarettes or smokeless tobacco in direct, face-to-face transactions (21 CFR 1140.14(c), 1140.16(c)).
- Not have in your facility tobacco vending machines or self-service displays unless you ensure that persons younger than 18 years of age are never present or permitted to enter at any time (21 CFR 1140.16(c)).
- Not break or otherwise open packages of cigarettes to sell or distribute single cigarettes or any package with less than 20 cigarettes (21 CFR 1140.14(d), 21 CFR 1140.16(b)).
- Not break or otherwise open packages of smokeless tobacco 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(d)).
- 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)).

### Restrictions on Advertising and Promotion of Tobacco Products<sup>2</sup>

Retailers of tobacco products MUST:

- Not offer any gift or item to any person purchasing cigarettes or smokeless tobacco in consideration of (a) the purchase of the cigarettes or smokeless tobacco product or (b) providing evidence of such purchase, such as credits, proofs-of-purchase, or coupons (21 CFR 1140.34(b)).
- Not sponsor 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)).

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 FFDCFA, as amended by the Tobacco Control Act. Under each schedule, violators are subject to increasing penalties for multiple violations within prescribed time periods.

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<sup>2</sup> The United States District Court for the Western District of Kentucky recently issued an order permanently enjoining FDA from enforcing section 21 CFR 1140.32(a). (Commonwealth Brands, Inc. v. United States, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)). In light of that order, as announced in the guidance document published on May 7, 2010, FDA intends to exercise its enforcement discretion concerning 21 CFR 1140.32(a) not to commence enforcement actions under this provision during the pendency of the litigation irrespective of whether the entity is a party to the pending lawsuit or located in the Western District of Kentucky (75 FR 25272).

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

- 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;
  - (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
  - (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. The FFDCFA further provides that the amount of civil money penalty ultimately assessed shall take into account, among other things, the degree of culpability of the violator.<sup>3</sup> FDA intends to promulgate regulations establishing standards for approved retailer training programs. In the interim, however, for retailers who wish to implement an effective training program for employees, FDA is issuing this guidance to provide recommendations on elements the agency believes should be included in such a

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<sup>3</sup> 21 U.S.C. § 333(f)(5)(B), as amended by the Tobacco Control Act.

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program. Until FDA promulgates these regulations, the agency intends to use the lower maximum civil money penalties schedule for all retailers who violate the regulations restricting the sale and distribution of cigarettes and smokeless tobacco products,<sup>4</sup> whether or not they have implemented a training program. However, FDA may consider further reducing the civil money penalty for retailers who have implemented a training program.

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 FFDCA, as amended by the Tobacco Control Act. Specifically, section 103(c) of the Tobacco Control Act amends section 303(f) of the FFDCA 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. Discussion**

#### **A. What definitions apply?**

FDA intends to use the following definitions in recommending elements for effective retailer training programs:

1. *Cigarette*: The term ‘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 filter, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco (21 CFR 1140.3(a)). This definition refers to a provision of the Federal Cigarette Labeling and Advertising Act 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).

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<sup>4</sup> The regulations were published in 75 FR 13225 (March 19, 2010).

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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 this chapter shall also apply to cigarette tobacco (21 CFR 1140.3(b)).
3. *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 (21 CFR 1140.3(i)).
4. *Retailer*: The term ‘retailer’ means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under the regulations (21 CFR 1140.3(h)).

### **B. What are the recommended elements to be included in a retailer training program?**

An effective retailer training program should ensure that employees:

(1) understand the tobacco access, advertising, and promotion restrictions of the Tobacco Control Act and implementing regulations; (2) verify that customers are of the legal age to purchase cigarettes and smokeless tobacco; and (3) successfully refuse purchase attempts by underage buyers.

FDA believes the following elements are important components of an effective retailer training program. These training program recommendations are based on the best available evidence to date.

#### *Training Program*

As soon as practicable, current employees should receive comprehensive training on the Federal laws and regulations restricting the access to, and the advertising and promotion of, tobacco products. New employees should receive the training prior to assuming job duties. This training should include detailed information on laws and regulations prohibiting the sales of cigarettes and smokeless tobacco to minors, as well as how to ask for and verify the age of customers. Training content should include, at a minimum, information on:

Applicable Laws and Penalties: Training content should describe Federal laws restricting the access to, and the advertising and promotion of, tobacco products. More specifically, this portion of the training should make clear that retailers of tobacco products must: (1) not sell cigarettes or smokeless tobacco to persons younger than 18 years of age (21 CFR 1140.14(a)); and (2) verify the age of purchasers of cigarettes or smokeless tobacco by means of photographic identification that contains the bearer’s date of birth for any person younger than 27 years of age (21 CFR 1140.14(b)).

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Training content should also include a discussion of the penalties for violations of those laws and regulations. FDA recommends that this portion of the training also cover the applicable State and local laws related to youth access to, and the advertising and promotion of, tobacco products, and discuss the penalties to both clerks and owners for violations of such laws.

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. One way to do this is to give employees the following information: “Tobacco products are responsible for approximately 440,000 deaths each year.<sup>5</sup> The Centers for Disease Control and Prevention (CDC) report an estimated 46 million people or 20.6 percent of all adults (aged 18 years and older) in the United States currently smoke cigarettes.<sup>6</sup> Paralleling this enormous health burden is the economic burden of tobacco use, which is estimated to total \$193 billion annually in medical expenditures and lost productivity.<sup>7</sup> According to the Substance Abuse and Mental Health Services Administration’s (SAMHSA) 2008 National Survey on Drug Use and Health, 80 percent of adults who are nicotine dependent report that they started smoking cigarettes before the age of 18.” This portion of the training should also explain that nicotine is an addictive substance and that virtually all new users of tobacco products are under the age of 18. Employees should be informed that one way to prevent the significant adverse consequences of tobacco use is to prevent youth from beginning to use these products.

Written Company Policies Against Sales to Minors: Retailers should adopt and enforce a written policy against sales to persons under the age of 18. This policy should be shared with all store personnel and retailer training content should describe company policies on preventing tobacco sales to persons under the age of 18.

Comprehensive Description of Tobacco Products Covered by Laws Prohibiting the Sale of Tobacco Products to Youth: The training curriculum should clearly define which products sold in the retail establishment are considered to be cigarettes and smokeless 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. FDA recommends that this portion of the training also clearly define which products sold in the retail establishment are included under State and local laws prohibiting sales of tobacco products to persons under the age of 18.

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<sup>5</sup> Centers for Disease Control and Prevention, Smoking and Tobacco Use Fact Sheet ([http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm) accessed 5/18/2010).

<sup>6</sup> Centers for Disease Control and Prevention. Cigarette Smoking Among Adults and Trends in Smoking Cessation—United States, 2008. Morbidity and Mortality Weekly Report 2009;58(44):1227–1232 (accessed 6/10/2010).

<sup>7</sup> CDC Fact Sheet.

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### Age Verification Requirements:

- Photographic Identification Requirements: Program content should clearly describe both Federal law and company policies on requiring identification, including the age that triggers photographic identification verification and acceptable forms of identification. Unless otherwise required by law, FDA recommends that retailers have in place a policy that only government-issued photographic identification (e.g., State-issued driver's license or identification card, military identification card, passport or immigration card) are acceptable for establishing a legal age to purchase cigarettes and smokeless tobacco products. FDA also recommends that the policy state that the photographic identification cannot be expired. FDA recommends that retailers include pictures of acceptable forms of identification in their training materials.
- 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 is above the legal age to purchase cigarettes and smokeless tobacco products and that the identification belongs to the person who is presenting it. 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 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 photographic identification without being asked, and appears to be over the age of 18.
- 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 include, but are not limited to: (1) 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; (2) examination of the identification to ensure any required watermarks or State seals are present; and (3) examination of the identification for visual clues as to 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). Training should also discuss how to determine whether an identification might have been altered and what an employee should do if an identification appears to be altered. Specifically, the training program should provide detailed information on signs of an altered photographic identification, which

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include but are not limited to: (1) any sign of tampering; (2) peeling lamination; (3) a different font on the date of birth or expiration date; and (4) smudged print.

- 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 and smokeless tobacco products;
  - Installing price scanners that are programmed so that when a tobacco product is scanned, the register displays a message prompting the employee to request age identification and key in the purchaser's date of birth;
  - Requiring employees to scan all photographic identifications through an electronic age verification device.
  
- Practical Guidance for Requesting Identification and Refusing Sales to Underage Youth: Training programs should include specific practical guidance for employees on when and how to:
  - Ask for photographic identification;
  - Ask for a second piece of identification;
  - Decline a sale when the customer has no photographic identification or when the identification shows the customer to be underage;
  - Decline a sale because of concerns related to the photographic identification's authenticity;
  - Decline purchase attempts by a minor made with written parental permission;
  - Resist customer pressure; and
  - Decline to sell cigarettes and smokeless tobacco to underage persons who are friends and acquaintances and the techniques for refusal.

FDA recommends that training programs incorporate role-playing (practice sessions with retail employees playing roles as clerks and customers) to ensure that employees can perform the tasks listed above adequately. Specifically, FDA recommends that training programs require store personnel to interactively practice the tasks listed above prior to

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performing these functions while on the job. Role-playing should include simulated sales transactions that address difficult situations such as addressing threats from customers and resisting pressure to sell to neighborhood youth.

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 tobacco sale if there is any question that doing so would violate the law.

Methods for Ensuring and Documenting that Employees Have the Knowledge Required to Comply with Laws Restricting the Access to, and Advertising and Promotion of, Tobacco Products: Retailers should require current and new employees to take a written test prior to selling tobacco products and should ensure that all employees receive a 70 percent or higher on the written test. Retailers should maintain written records documenting that all individual employees have been trained, including: (1) a copy of the test given to employees and the correct answers, and (2) 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. Retailers should retain the written 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).

#### *Training Frequency*

Current employees should be trained as soon as practicable. New retail employees should be trained prior to starting work. All employees should receive refresher training, including a written test, 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 or smokeless tobacco to persons under the age of 18.

#### *Training Methods*

The training curriculum may be delivered by a trainer in a classroom setting, via written materials provided to store personnel for self-study, or via Web or other computer-based applications.

### **C. What hiring and management practices are elements of an effective retailer training program?**

FDA recommends that appropriate retailer hiring and management practices be implemented as part of a comprehensive retailer training program intended to reduce the illegal sale of tobacco products to persons under the age of 18.

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### *Hiring Practices*

Applicants for positions that involve selling tobacco should be notified both verbally and in writing of the importance of complying with laws prohibiting the sale of cigarettes and smokeless tobacco to youth, and should be required to sign an acknowledgement stating that they have read and understand the information. Current employees should be given these notifications and should be required to sign an acknowledgement stating that they have read and understand the information.

Retailers should consider requiring clerks who sell tobacco to be at least 18 years of age. This is because studies have shown that clerks under the age of 18 are more likely to sell tobacco to minors than are older clerks.

### *Management Practices*

Retailers should consider implementing an internal compliance check program, also known as a mystery shopper program. In this type of program, retailers use either a person of legal age who is younger than 27 years old (to test whether clerks are requesting photographic identification) or a person who is under the legal age to buy tobacco (to test whether clerks are both requesting photographic identification and refusing to make a sale to underage youth). Internal compliance checks should be performed at random and varying times of the day and at least once every six months. Employees who fail the internal compliance check should be notified immediately and given additional training. Employees who pass the compliance check should be congratulated and the employee's supervisor should be informed of the success. Retailers should also consider rewarding employees who pass the internal compliance check with a tangible reward, such as a cash bonus or time off.

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 and smokeless tobacco to underage youth. Specifically, retailers should review the tapes to ensure that store personnel are requesting and examining photographic identification from customers who appear to be under the age of 27.

Retailers should consider establishing company policies that take employee performance on compliance checks into account in company decisions about compensation, promotion, and retention. In particular, retailers should strongly consider establishing disciplinary sanctions for employee noncompliance. FDA recommends that retailers document the procedures and corrective actions for their internal compliance check program.

To ensure that management has a vested interest in clerk compliance with laws prohibiting the sale of cigarettes and smokeless tobacco to underage youth,

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retailers should also consider making a store's compliance rate a component of a retail supervisor's performance reviews.

### **D. How will civil money penalties 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 maximum civil money penalties for violations of restrictions promulgated under section 906(d) of the FFDCa, as amended by the Tobacco Control Act, pertaining to the sale and distribution of a tobacco product, including access, promotion, and advertising 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. The FFDCa further provides that the amount of the penalty ultimately assessed shall take into account, among other things, the degree of culpability of the violator.<sup>8</sup>

Retailers are under no obligation to submit their training programs for FDA review since this is a voluntary program. Until FDA promulgates regulations establishing standards for approved retailer training programs, the agency intends to use the lower maximum civil money penalties schedule for all retailers who violate the regulations restricting the sale and distribution of cigarettes and smokeless tobacco products,<sup>9</sup> whether or not they have implemented a training program. However, FDA may consider further reducing the civil money penalty for retailers who have implemented a training program.

Retailers who have received a notice of Complaint for Civil Money Penalties and who wish to submit evidence that they have a training program in place may do so after receiving the Complaint. Until FDA promulgates regulations establishing standards for approved retailer training programs, the agency will consider any evidence of a training program (e.g., the training curriculum, the test provided to employees and their test scores, etc.) in determining whether to further reduce the civil money penalty for retailers who violate the regulations.

Detailed information on where to send evidence that a retailer has a training program in place will be included in the notice of Complaint for Civil Money Penalty.

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<sup>8</sup> 21 U.S.C. § 333(f)(5)(B), as amended by the Tobacco Control Act.

<sup>9</sup> The regulations were published in 75 FR 13225 (March 19, 2010).