



# UNDERSTANDING FDA REQUIREMENTS

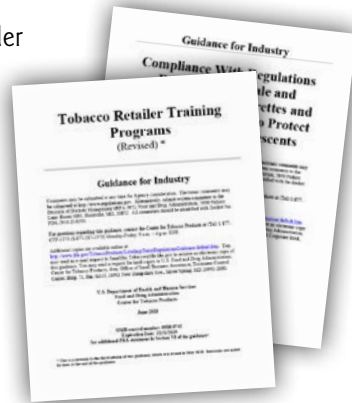
We Card's Summary for Retailers

Information as of November 2019

Dear Retailer:

In order to comply with the federal law (Tobacco Control Act) and all the FDA Rules and Regulations, there is a lot of information to know and understand.

Just because you always “card” under 27 year old customers and deny illegal sales to minors doesn’t mean you are in full compliance.



**We Card’s Summary for Retailers** condenses the FDA compliance information into this single document—gleaned largely from these sources:

- [The Tobacco Control Act](#).
- FDA Guidance [Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents](#)
- FDA Guidance [Tobacco Retailer Training Programs](#)

We are not lawyers, and we’re not providing legal advice here. We do hope that this information is useful to bring your retail store(s) into compliance.

When new regulations or compliance information changes, we will do our best to provide you with updates.

Thank you.

Doug Anderson  
President  
The We Card Program, Inc.

## TABLE OF CONTENTS

### SALES AND DISTRIBUTION REQUIREMENTS..... PAGE 2

- Card “under 27” year old customers
- No Sales to Minors requirements
- No free samples of cigarettes, remove or bring into compliance all self-service displays
- and much more.

### ADVERTISING, LABELING, AND PROMOTION REQUIREMENTS..... PAGE 3

- Allowed to advertise in newspapers?
- What about FDA’s 30-Day Advance Notice requirement for online and electronic advertising?
- Find out what FDA allows, prohibits and what are the exceptions

### FDA ENFORCEMENT..... PAGE 4-5

- Compliance Checks of Retailers
- Fines and Penalties
- Is there an FDA “approved training program”?

### DEFINITIONS..... PAGE 6-7

Terms used by FDA

- *Retailer*
- *Point of Sale*
- *Direct, Face-to-Face Exchange*
- *Self-Service Display*
- *Qualified Adult-Only Facility*

DISCLAIMER: This information summary is provided as a service of The We Card Program, Inc., but is not intended to provide legal advice or analysis. These summaries are not intended to be complete representations of federal law or FDA guidance, which change from time to time and may contain additional rules and restrictions relating to tobacco products not mentioned in this summary. Retailers should not rely on these summaries as complete or accurate descriptions of applicable federal law or guidance.

# FDA Requirements: SALES AND DISTRIBUTION REQUIREMENTS



## UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers  
Information as of November 2019

### FDA Retailer Regulations Overview *as of November 2019*

**ENDS** include e-cigarettes, e-hookah, ecigars, vape pens, advanced refillable personal vaporizers, electronic pipes, components & parts (such as e-liquids, atomizers, tank systems, batteries)

RESTRICTED PRODUCTS:								
REQUIREMENTS	Cigarettes, Cigarette Tobacco & Roll-Your-Own Tobacco	Smokeless Tobacco	Cigars	Hookah & Pipe Tobacco	Nicotine Gels	Dissolvable Tobacco Products	Electronic Nicotine Delivery Sales (ENDS)	
<b>CHECK PHOTO ID</b> of everyone under age 27 who attempts to purchase.	✓	✓	✓	✓	✓	✓	✓	
<b>NO UNDERAGE SALES</b> Follow state & local minimum age laws*	✓	✓ <b>Minimum Age Law</b>	FDA requires denying sales to under 18 year old customers—if your state or city has a higher minimum age, such as 19, 20 or 21 years old, you <b>MUST</b> follow that minimum age. See We Card's list of state and city minimum-age requirements: <a href="http://wecard.org/minimum-age-laws">wecard.org/minimum-age-laws</a>					✓
<b>NO VENDING</b> Do NOT sell in a vending machine	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	
<b>NO SELF-SERVICE</b> Only sell in a direct face-to-face exchange.	✓ See Exception <sup>1</sup>	✓ See Exception <sup>1</sup>	-	-	-	-	-	
<b>NO FREE SAMPLES</b> Do NOT give away free samples, including any of their components or parts.	✓	✓ See Exception <sup>1</sup>	✓	✓	✓	✓	✓	
<b>NO FLAVORED PRODUCTS</b> Do NOT sell flavored product – a product that contains a characterizing flavor (except menthol or tobacco flavor)	✓	-	-	-	-	-	-	
<b>OTHER</b>	Do NOT sell cigarette packages containing fewer than 20 cigarettes or single cigarettes, know as "loosies."	Do NOT break open packages to sell products in smaller amounts.	<b>Required Sign</b> For Cigars sold Individually without packaging, you must post a specific sign at each POS. <sup>3</sup>	-	-	-	-	

1 Exception: Only allowed in Qualified Adult-Only facilities where no minor is permitted to enter or be present (follow the minimum-age requirement of your state and locality).  
 2 See FDA regulations for tobacco product manufacturers at: <http://www.fda.gov>  
 3 Required by FDA deadline of Aug. 10, 2018. See FDA regulation: <https://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm524442.htm#individually>  
 \* FDA set the national minimum-age for legal sales at 18 years old BUT also requires you to follow your state or local law if it has a higher age limit (such as 19 or 21).

Do NOT sell without a health warning label.

**MANUFACTURER REGULATIONS MAY APPLY TO ENDS SALES**  
Retail establishments, such as **vape shops, that mix and/or prepare e-liquids or assemble vaporizers are considered "tobacco product manufacturers."** MANY separate regulations will apply. See FDA regulations for tobacco product manufacturers.<sup>2</sup>

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## Warning Statement Requirements **COMPLIANCE DEADLINE: AUGUST 10, 2018** SEE EXCEPTION on next page

### Retailers MUST:

- 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."
- 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)).
  - (i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
  - (ii) WARNING: Cigar smoking can cause lung cancer and heart disease.
  - (iii) WARNING: Cigars are not a safe alternative to cigarettes.
  - (iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
  - (v) (A) WARNING: Cigar use while pregnant can harm you and your baby.; or  
(B) SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
  - (vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.
- For Cigars Sold Individually without Packaging—Retailers who sell cigars individually, and not in a product package must post a sign at each point-of-sale that displays all six of the required statements. Each sign must be at least 8.5 x 11 inches in size and meet other requirements, such font and font size. The signs must be placed on or within 3 inches of each cash register. [Download We Card's Sign](#)

Find more helpful information at [www.wecard.org](http://www.wecard.org)



## UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers  
Information as of November 2019

## FDA Requirements: ADVERTISING, LABELING, AND PROMOTION REQUIREMENTS

- Prohibits the sponsorship of 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.
- Prohibits the sale or distribution of items, such as hats and tee shirts, with cigarette and smokeless tobacco brands or logos.
- Requires that audio ads use only words with no music or sound effects.

### Warning Statement Requirements **COMPLIANCE DEADLINE: AUGUST 10, 2018**



#### EXCEPTION FOR CIGARS AND PIPE TOBACCO

The United States District Court for the District of Columbia recently issued an order enjoining FDA from enforcing the health warnings requirements for cigars and pipe tobacco . . . FDA intends to comply with the court's order . . ." and FDA "does not intend to enforce the labeling requirements for cigars and pipe tobacco while the injunction is in effect . . ."

### Retailers MUST:

- 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.”
- 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)).
  - (i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
  - (ii) WARNING: Cigar smoking can cause lung cancer and heart disease.
  - (iii) WARNING: Cigars are not a safe alternative to cigarettes.
  - (iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
  - (v)(A) WARNING: Cigar use while pregnant can harm you and your baby;  
or  
(B) SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
  - (vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.

Find more helpful information at [www.wecard.org](http://www.wecard.org)

**Sources of Information:** Sources: FDA Guidance *Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (August 2013). FDA Guidance *Tobacco Retailer Training Programs, The Tobacco Control Act, Cigar Labeling and Warning Statement*

## FDA Enforcement: COMPLIANCE CHECKS OF RETAILERS



## UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers  
Information as of November 2019

### About Compliance Check Inspections

- Some Compliance Check Inspections involve the use of a minor under the supervision of inspector(s)
- A minor under the age of 18 will attempt to purchase a regulated tobacco product (currently that means a cigarette, cigarette tobacco, or a smokeless tobacco product) to determine compliance with the age and identification requirements of the law
- Inspections are unannounced and you may not immediately know they occurred
- Other inspections may be done without using minors to see if your retail establishment complies with all other requirements of the law
- The inspectors may announce themselves when doing inspections not involving minors and issue you an official FDA Form 482 – Notice of Inspection
- In addition, they may ask you questions

### FDA Form 482 – Notice of Inspection

- FDA Form 482 explains FDA's authority to enter and inspect a retail establishment.
- May be issued during inspections done to determine if the establishment complies with requirements of the law
- This form does not list any observed potential violations



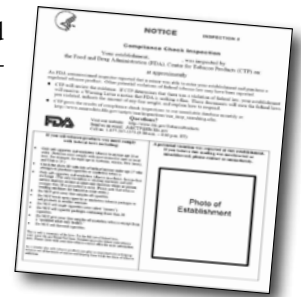
### Compliance Check Inspection Notifications

- Are sent for inspections where minor was able to enter a retail establishment and purchase a regulated tobacco product
- FDA is sending these documents to provide the retailer with notification that a potentially violative inspection involving a minor has occurred at their establishment, and to inform the retailer of the date and approximate time that the inspection occurred
- Notifications are sent via UPS

- FDA began sending these notifications July 2012
- The notification also serves to inform the retailer that FDA will make a final determination regarding whether there has been a violation of federal law.
- What to do if you receive a Compliance Check Inspection Notification
- A retailer is not required to contact FDA after they have received this notification.
- If a retailer feels that there has been an error regarding the location or address of their establishment, they should notify FDA. If there is such an issue, retailers should contact FDA at the phone number or email address on the notification

### Compliance Check Inspection Notifications

- FDA will review the evidence collected by the inspector and make a determination if there was a violation
- If FDA determines that there was a violation of federal law, the establishment will receive:
  - A Warning Letter; or
  - A notice FDA is seeking a fine called a Civil Money Penalty; or
  - A notice that FDA is seeking a No-Tobacco-Sale Order



### What to do if you receive a Compliance Check Inspection Notification

- Retailers can check the results of Compliance Check Inspections in our searchable database
- Updated monthly
- Available at: <http://go.usa.gov/Ebd> (case sensitive)

Source: Compliance Check Inspection Notifications, Compliance Training for Tobacco Retailers, David Keith, Office of Compliance and Enforcement, CTP, September 5, 2012.

Find more helpful information at [www.wecard.org](http://www.wecard.org)

**Sources of Information:** Sources: FDA Guidance *Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (August 2013). FDA Guidance *Tobacco Retailer Training Programs, The Tobacco Control Act, Cigar Labeling and Warning Statement*

## FDA Enforcement: FDA FINES & PENALTIES



## UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers  
Information as of November 2019

### Federal Law: FDA Enforcement—Penalties and Fines & more

#### What happens if a retailer is found to be in violation of these regulations?

FDA has a variety of enforcement tools to address retailers who violate the regulations, including civil money penalties, warning letters, seizures, injunctions, and/or criminal prosecution. Retailers who violate the regulations may also be in violation of state law and subject to a variety of state remedies.\*

#### “Retail establishments are responsible for providing training to their employees.”

[www.fda.gov](http://www.fda.gov) Frequently Asked Questions: Protecting Kids From Tobacco

#### FDA FINES & PENALTIES

# of Violations	Fine
1st	Warning Letter
2 within 12 months	\$292
3 within 24 months	\$584
4 within 24 months	\$2,340
5 within 36 months	\$5,849
6 within 48 months	\$11,698
5 or more within 36 months	No Sale Order

as of 11-5-19



#### WHAT IS AN FDA “APPROVED TRAINING PROGRAM?”

An FDA “approved training program” has yet to be defined by the FDA. What is known thus far is that the federal law allows for an FDA “approved training program” that may provide to any retailer that implements the “approved training program,” a reduced civil money penalty if that same retailer is found to be in violation. The FDA does not require training of retail employees, but it recommends retailers train and educate their employees.

When the FDA makes it clear, we'll let you know!

**In the meantime, be prepared!  
Get We Card Trained!**

\*Sources of Information: [www.fda.gov](http://www.fda.gov), Frequently Asked Questions: Protecting Kids From Tobacco Fine Chart: Sources of Information: [www.fda.gov](http://www.fda.gov), The Family Smoking Prevention and Tobacco Control Act – Public Law 111-31.

Find more helpful information at [www.wecard.org](http://www.wecard.org)

**Sources of Information:** Sources: FDA Guidance *Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (August 2013). FDA Guidance *Tobacco Retailer Training Programs, The Tobacco Control Act, Cigar Labeling and Warning Statement*

## FDA Requirements: DEFINITIONS



## UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers  
Information as of November 2019

### DEFINITION OF RETAILER

The term **retailer** includes 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 [these regulations].”<sup>1</sup>

This definition applies regardless of the number of products sold or the price at which they are sold.

For example, even if Store A generates most of its sales from selling food products, and cigarettes sales represent only a fraction of total sales, the store is a “retailer” subject to regulation under part 1140. The store will be a retailer regardless of whether it sells above cost, at cost, or below cost.

Retailers also include persons who operate facilities where vending machines or self-service displays (or merchandisers) of cigarettes and/or smokeless tobacco are located, even if they technically do not own the vending machines or self-service displays themselves.

Note that the definitions of distributor, manufacturer, and retailer are not mutually exclusive. In other words, you can be a manufacturer, distributor, and retailer if you engage in actions that fall within each of the definitions. For example, if you make finished cigarettes and sell them to individuals for personal consumption, you are a manufacturer (because you made the cigarettes) and a retailer (because you sold them to individuals).

### DEFINITION OF POINT OF SALE

#### What Is Point of Sale?

The term **point of sale** means “any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.”<sup>2</sup> In other words, point of sale does not have to be fixed in one location or the same location (although most points of sale will probably be fixed structures such as stores). For example, if you sell cigarettes from a truck, any advertising and marketing materials that appear on the truck, or at the location where consumers purchase the product, or that are given to consumers at the time of purchase, would be point-of-sale materials.

### DEFINITION OF “DIRECT, FACE-TO-FACE EXCHANGE”

#### What does FDA mean by a “direct, face-to-face exchange?”

Retailers are required to physically hand the product to the consumer. This means that, if you are a retailer, you and your employees must:

- see the customer directly, without the use of electronic aids (such as a television screen) or mechanical devices (such as an intercom), and, if necessary, verify that he or she is at least 18 years old;
- obtain the product for the customer; and
- hand the product to the customer.

This requirement also helps retailers to verify the customer's age and to prevent children from shoplifting these products. Shoplifting is another means of cigarettes and smokeless tobacco products getting into the hands of children.

### DEFINITION OF SELF-SERVICE DISPLAY

#### What is a “self-service display” under the regulations?

A self-service display is any item that permits a consumer to access and remove cigarettes or smokeless tobacco products without a direct, face-to-face exchange between the retailer and the customer. Self-service displays, which also may be referred to as “merchandisers,” come in many different shapes and sizes, ranging from free-standing, multishelf kiosks to small display stands that are placed next to a cash register.

Regardless of the type or size, a self-service display is not a permissible method of selling cigarettes or smokeless tobacco in any facility (e.g., pharmacy, convenience store, grocery store, gas station, restaurant) where anyone younger than 18 years of age is present, or permitted to enter, at any time. So, if anyone younger than 18 years of age is present in, or is permitted to enter, your retail facility at any time, you cannot use self-service displays and vending machines to sell cigarettes or smokeless tobacco products.

To qualify as a facility where individuals under 18 years of age are neither present nor permitted to enter at any time for purposes of having vending machines or self-service displays, all employees in the facility would need to be 18 years of age or older.

See Definition of [Qualified Adult-Only Facility](#).

<sup>1</sup> 21 CFR 1140.3(h).

<sup>2</sup> 21 CFR 1140.3(g)



## FDA Requirements: DEFINITIONS

### DEFINITION OF QUALIFIED ADULT-ONLY FACILITY

Under the regulations, the term “qualified adult-only facility” means a facility or restricted area that:

1. requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity a government-issued identification showing a photograph and a date of birth indicating the holder is at least 18 years of age (state law may require persons to be older than 18 in some states);
2. does not sell, serve, or distribute alcohol;
3. is not located next to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;
4. is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco adhering to this subparagraph; and
5. is enclosed by a barrier that:
  - a. is constructed of, or covered with, an opaque material (except for entrances and exits);
  - b. extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling);
  - c. prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and
  - d. does not display on its exterior —
    - any tobacco product advertising;
    - a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or
    - any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate § 1140.34(c).

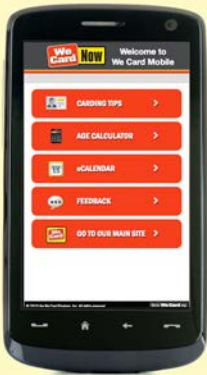
For more information, see [FDA Guidance](#).

**More ways to get ready:**



**ABOUT WE CARD**

The We Card Program is a national non-profit organization focused on ensuring that age-restricted product retailers are fully educated, trained and prepared to reject underage sales.



**When you need We Card at your fingertips!**



[wecardnow.com](http://wecardnow.com)



**UNDERSTANDING FDA REQUIREMENTS**

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Information as of November 2019

**Equip Your Stores**


Call 1-800-934-3968 or visit [wecard.org](http://wecard.org).



**Train Employees**



Award-winning training in the *We Card eLearning Center*.


## eLearning Center



**EMPLOYEE TRAINING**


Award-winning training, now even better!







**REFRESHER TRAINING**


Additional interactive exercises and more practice in the steps employees need to prevent tobacco sales to minors.





**MANAGER TRAINING**

Built to be LMS-ready and SCORM-compliant. Ask for a test drive on your LMS!



**Mystery Shopping**

We Card offers the *ID Check-Up* mystery shopping service at a low cost of \$26 per mystery shop which allows even the smallest retail store to participate in an ID checking system that is proven to increase carding rates.



**LINKS TO FDA RESOURCES**

[FDA Rules and Regulations](#)

[FDA Guidance on Tobacco Retailer Training Programs](#)

[Search FDA's Compliance Check Data for your store\(s\)](#)

**WE CARD RESOURCES at [www.wecard.org](http://www.wecard.org)**

**We Card's Guide to Best Practices**

An interactive PDF. Take our survey and get this free download.

**Understanding FDA Requirements**

We Card's Summary for Retailers

**We Card's Training Resource Center**

State law summaries, state sign requirements, FDA information and many other resources.

**Company Tobacco Sales Policy & Employee Acknowledgment of Company Policy**

A recommended template. Customize it for your company.