

UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers

Information as of September 2014

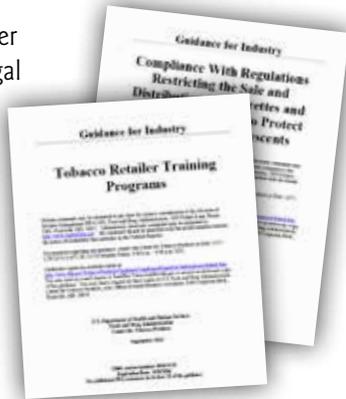
Dear Retailer:

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](#) (August 2013).
- FDA Guidance [Tobacco Retailer Training Programs](#) (September 2013).



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.

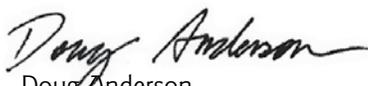

 Doug Anderson
 President
 The We Card Program, Inc.

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Terms used by FDA

- *Retailer*
- *Cigarette, Cigarette Tobacco and Smokeless Tobacco*
- *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



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- Check photo ID of everyone appearing under age 27 who attempts to purchase cigarettes, cigarette tobacco, or smokeless tobacco.
- Only sell cigarettes, cigarette tobacco, and smokeless tobacco to anyone age 18 or older. *
 - * Retailers must also follow state or local tobacco laws, even if they are more restrictive. For example, in some states the minimum age is 19 – AL, AK, NJ & UT.
- Only sell cigarettes, cigarette tobacco, and smokeless tobacco in a direct, face-to-face exchange. **
- Do NOT give away free samples of smokeless tobacco except from a “qualified adult-only facility.”
 - See the definition of [Qualified Adult-Only Facility](#)
- Do NOT sell flavored cigarettes or flavored cigarette tobacco (other than menthol).
- 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(e)).

** Prohibits the sale of cigarettes and smokeless tobacco in vending machines, self-service displays, or other impersonal modes of sales, except in very limited situations.

See the definition of [Direct, Face-to-Face Exchange](#)
See the definition of [Self-Service Display](#)

Exception: The sale of cigarettes, cigarette tobacco, and smokeless tobacco through vending machines and self-service displays are allowed in qualified adult-only facilities where no person younger than 18 is permitted to enter.

See the definition of [Qualified Adult-Only Facility](#)

Important: Some state laws prohibit tobacco product vending machines. Check your state law.

- Do NOT break open cigarette or smokeless tobacco packages to sell products in smaller amounts.
- Do NOT sell cigarette packages containing fewer than 20 cigarettes.
- Do NOT sell single cigarettes, also called “loosies.”
- Do NOT give away free samples of cigarettes.



WHAT DOES THIS MEAN?

Remove all vending machines and self-service displays UNLESS you operate a “Qualified Adult-Only Facility”

See the definition of [Qualified Adult-Only Facility](#)
See the definition of [Self-Service Display](#)

Comply with all Advertising, Labeling and Promotion Requirements

See [Advertising, Labeling and Promotion Requirements](#)

FDA Requirements: ADVERTISING, LABELING, AND PROMOTION REQUIREMENTS



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- Prohibits the sale of cigarettes and smokeless tobacco in vending machines, self-service displays, or other impersonal modes of sales, except in very limited situations.

See the definition of [Self-Service Displays](#)

Exception: The sale of cigarettes, cigarette tobacco, and smokeless tobacco through vending machines and self-service displays are allowed in qualified adult-only facilities where no person younger than 18 is permitted to enter.

See the definition of [Qualified Adult-Only Facility](#)

Important: Some state laws prohibit tobacco product vending machines. Check your state law.

- 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.

Some forms of advertising require FDA notification

- Requires retailers to notify FDA 30-days before using advertising or labeling for FDA regulated tobacco products (except in “permissible forms of advertising”)

FDA Requirement: *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 in a medium that is not listed in 21 CFR 1140.30(a)(1).*



WHAT DOES THIS MEAN?

Retailers may advertise for FDA tobacco regulated products in their stores and in other “permissible forms” of advertising (shown in figure 1 in green box) with no requirement to notify the FDA.

Other forms of advertising REQUIRE retailers to notify the FDA 30-days in advance (shown in figure 1 in yellow box).

FDA NOTIFICATION REQUIREMENTS

FORMS OF ADVERTISING

No Notice Required to FDA

Permissible Forms of Advertising as listed in 21 CFR 1140.30(a)(1)

- newspapers
- magazines
- periodicals or other publications (whether periodic or limited distribution)
- billboards, posters, and placards;
- non-point-of-sale promotional material (including direct mail)
- point-of-sale promotional material;
- audio or video formats delivered at a point of sale.

Required 30-day Advance Notice to FDA

Electronic and Online Advertising – Forms of electronic and on-line media that require notification include, but are not limited to:

- Internet Web sites
- Product placements in movies, music videos, and television, if done at the expense of tobacco manufacturer, distributor, or retailers
- Blogs or weblogs (e.g., Blogger, WordPress, Tumblr)
- Emails sent to consumers
- Microblogs (e.g., Twitter)
- Podcasts (e.g., audio sharing)
- Social networks and online communities (e.g., Facebook, MySpace, LinkedIn, Friendster)
- Video sharing (e.g., YouTube, Blip tv, Vimeo)
- Widgets or window gadgets
- Wikis (e.g., Wikipedia)
- Applications for smart phones and tablet computers (e.g., iPhones, Androids, iPads)
- Text messaging
- Instant messaging
- Pop up or roll-over advertisements on Web sites

Notice to FDA

The notice to the FDA must describe the medium intended to be used and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The notice must be sent to:

Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850-3229

For more information (such as what FDA requests within the notification), see [FDA Guidance](#).

Find more helpful information at 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* (September 2013). *The Tobacco Control Act*.

FDA Enforcement: COMPLIANCE CHECKS OF RETAILERS



UNDERSTANDING FDA REQUIREMENTS

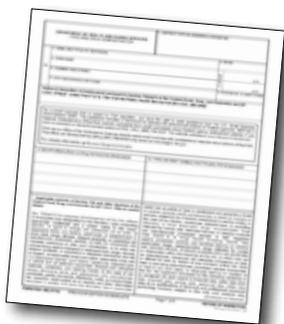
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About Compliance Check Inspections

- 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



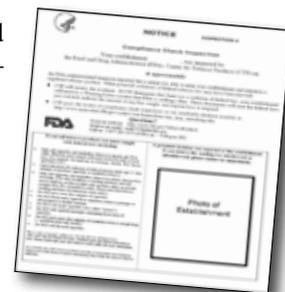
Compliance Check Inspection Notifications

- 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

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* (September 2013). *The Tobacco Control Act*.

FDA Enforcement: FDA FINES & PENALTIES



UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers
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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 Frequently Asked Questions: Protecting Kids From Tobacco

FDA FINES & PENALTIES		
# of Violations	Fine	Fine*
1st	\$250	Warning Letter
2nd in 12 months	\$500	\$250
3rd in 24 months	\$1,000	\$500
4th in 24 months	\$2,000	
5th in 36 months	\$5,000	
6th or more	\$11,000	
Repeated	No Sale Order	

*Reduced fine with FDA “approved” training program.



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. Frequently Asked Questions: Protecting Kids From Tobacco Fine Chart: Sources of Information: www.fda.gov. The Family Smoking Prevention and Tobacco Control Act – Public Law 111-31.

Find more helpful information at 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* (September 2013). *The Tobacco Control Act*.

FDA Requirements: DEFINITIONS



UNDERSTANDING FDA REQUIREMENTS

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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].”¹

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.”² 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](#).

¹ 21 CFR 1140.3(h).

² 21 CFR 1140.3(g)

FDA Requirements: DEFINITIONS

DEFINITION OF CIGARETTE, CIGARETTE TOBACCO AND SMOKELESS TOBACCO

FDA regulations apply to some, but not all, tobacco products.

Specifically, the regulations apply to cigarettes, including roll-your-own tobacco;¹ cigarette tobacco; and smokeless tobacco. These items are defined as:

- The term **cigarette** as defined in section 900(3) of the FD&C Act (and § 1140.3(a))
 - “(A) means a product that —
 - (i) is a tobacco product; and
 - (ii) 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 3(1) of the Federal Cigarette Labeling and Advertising Act (FCLAA) defines the term “cigarette” to mean:

“(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).”

A tobacco product may also meet the definition of a “cigarette” if it contains “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.”² Accordingly, a tobacco product that meets the definition of a “cigarette,” even if it is not labeled as a “cigarette” or is labeled as a cigar or as some other product, may be subject to the regulations.³ In other words, a product is a “cigarette” despite any other names that may be used to describe it, if its appearance, the kind of tobacco used in its filler, or the packaging and labeling indicates that it is likely to be offered to a consumer or bought by the consumer as a cigarette. In addition, roll-your-own tobacco also meets the definition of cigarette and is thus subject to the restrictions in these regulations.



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Currently, other tobacco products, such as cigars, little cigars, and pipe tobacco, are not subject to these regulations.

The term **cigarette** tobacco is defined in section 900(4) of the FD&C Act and in § 1140.3(b) as “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.” *Under the FD&C Act and these regulations, cigarette tobacco is treated the same as cigarettes unless specifically stated otherwise.* Thus, cigarette tobacco is subject to the restrictions in these regulations.

The term **smokeless tobacco** is defined in section 900(18) of the FD&C Act and in § 1140.3(i) as “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*” (emphasis added). There are many types of smokeless tobacco. The principal names for the various types of smokeless tobacco include: moist snuff; snus; dry snuff; loose leaf chewing tobacco; plug chewing tobacco; and twist chewing tobacco.

Please note that the regulations do not make any distinction between domestic cigarettes or smokeless tobacco products and products that are imported into the United States. If you import, distribute, or offer imported cigarettes or smokeless tobacco products for sale in the United States, you and your products must comply with these regulations.

¹ The definition of “cigarette” includes roll-your-own tobacco. See Section 900(3) of the FD&C Act; 21 C.F.R. 1140.3(a).

² Section 900(3) of the FD&C Act and 21 CFR 1140.3(a). See also guidance to industry and FDA staff entitled *General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors* (Edition 2), FDA/CTP, (Dec. 23, 2009) (guidance on General Q&As on Flavored Tobacco), at Question 6, available at <http://www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/UCM195420.pdf>.

³ See guidance on General Q&As on Flavored Tobacco, at Question 5.

FDA Requirements:

DEFINITIONS



UNDERSTANDING FDA REQUIREMENTS

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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](#).

Find more helpful information at 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* (September 2013). *The Tobacco Control Act*.

More ways to get ready: RESPONSIBLE RETAILING RESOURCES



UNDERSTANDING FDA REQUIREMENTS

We Card's Summary for Retailers
Information as of December 2013

GET RESOURCES

Click to download or access resources

[Get We Card's Guide to Best Practices](#)

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

[Take We Card's online Training](#)

An employee Training Course is available with FDA content. Manager Training Course is available with FDA content. Manager Training Course and a Refresher Training Course are available now.

[ID Check-Up](#)

A confidential mystery shopping service to check your store's performance at carding customers.

[State Law Summaries](#)

Find out about the laws in my state—including fines and penalties.

[State Sign Requirement](#)

In some states, retailers are fined for not having the legally required signs posted. Find out what the signs look like in your state.

[Minor License Visual Characteristics](#)

Find out what the minor license in your state looks like.

[Company Tobacco Sales Policy and Employee Acknowledgment of Company Policy](#)

We Card's recommended template you can use to customize for your company.

[Get We Card Signage and Training Tools](#)

Order online or [download a We Card Catalog](#)



LINKS TO FDA RESOURCES

[FDA Guidance](#)

[FDA Rules and Regulations](#)

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

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[FDA Tobacco Compliance Webinars](#)

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