

Compliance Training for Tobacco Retailers Warning Letters

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Office of Compliance and Enforcement

Center for Tobacco Products

October 4, 2011

Agenda

- FDA Authority and Retailers
- Compliance Check Inspections
- What if Violations are not Observed?
- What if Violations are Observed?
- What information do Warning Letters contain?
- Examples of Violations
- Will a retailer know that a Warning Letter has been issued?
- What should a retailer do if they receive a Warning Letter?

What Authority Does FDA Have

- The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.
- Tobacco Products that FDA currently has authority over
 - Cigarettes
 - Smokeless tobacco
 - Loose cigarette tobacco
- The authority to inspect retailers

What is a Retailer?

- You are a retailer for purposes of these regulations if you sell cigarettes, smokeless tobacco, or loose cigarette tobacco to individuals for their own use or operate a facility where a vending machines or self-service display is present.
- The regulations apply to all types of retail establishments, such as, grocery stores, pharmacies, convenience stores, gas stations, bars, restaurants, bowling alleys, and hotels.

How Will FDA Be Inspecting Retailers?

- The Tobacco Control Act requires FDA to contract with states and territories, where feasible, to inspect retail establishments within their jurisdiction
- FDA can also use their own personnel and to take enforcement action when appropriate
- FDA will determine if retailers are complying with the Act and regulations by performing compliance check inspections at the retail establishment

What Are Some of the Things That FDA Will Be Looking For ?

- That you DO check the photo ID with date of birth of anyone under age 27 who attempts to purchase cigarettes, smokeless tobacco, or loose cigarette tobacco
- That you DO only sell cigarettes, smokeless tobacco, and loose cigarette tobacco to individuals age 18 or older. (Retailers must also comply with more restrictive state or local laws. For example, the legal age in Alabama, Alaska, New Jersey, and Utah is 19.)

What Are Some of the Things That FDA Will Be Looking For ?

- That you DO only sell cigarettes, smokeless tobacco, and loose cigarette tobacco in a direct, face-to-face exchange. (The only exception is vending machines and self-service displays located in facilities or locations where no person younger than 18 is permitted to enter at any time. Please note that tobacco vending machines are banned under some state or local laws.)

What Are Some of the Things That FDA Will Be Looking For ?

- If a vending machine or self-service display is present, that you DO NOT allow minors to be present or permitted in the facility or location at any time.
- That you DO NOT give away free samples of cigarettes. That you DO NOT break open cigarette or smokeless tobacco packages to sell products in smaller amounts.
- That you DO NOT sell single cigarettes (also called “loosies”).
- That you DO NOT sell cigarette packages containing fewer than 20 cigarettes.

What are Some of the Things that FDA Will be Looking for ?

- That you DO NOT offer free samples of smokeless tobacco except from a “qualified adult-only facility.”
- That you DO NOT sell or give away items – such as hats, t-shirts, or lighters – with tobacco brands or logos.
- That you DO NOT offer gifts or items in exchange for the purchase of cigarettes, smokeless tobacco, or loose cigarette tobacco, or in exchange for tobacco product proofs-of-purchase, coupons, or credits.
- That you DO NOT sell flavored cigarettes

Will I know That FDA Is Inspecting Me?

- Compliance check inspections are unannounced
- Often you will not know that FDA has been there
- FDA inspector may announce themselves
- If so they will issue you an Inspection Form 482
– Official Notice of Inspection
- This document explains FDA's authority to enter and inspect a retail establishment under Section 704 of the FD&C Act.

Copy Of FDA Form 482

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO.	
2. NAME AND TITLE OF INDIVIDUAL		3. DATE	
4. FIRM NAME		5. TIME OF DAY	
6. NUMBER AND STREET		6. P.M.	
7. CITY AND STATE & ZIP CODE		8. PHONE NO. & AREA CODE	
<p>Notice of inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 342(a)] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264].</p> <p>As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman</p> <p>FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-9530 or by email at ombuds@fdac.fda.gov.</p> <p>For industry information, go to www.fda.gov/industry.</p>			
9. SIGNATURE(S) (Food and Drug Administration Employee(s))		10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))	
<p>* Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:</p> <p>Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (Continued on Reverse)</p>		<p>(C) "Every manufacturer of electronic products shall establish and maintain records (including testing records) which contain and provide such information as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted in conformity with this Act and standards prescribed pursuant to this Subpart and also, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted in conformity with this Act and standards prescribed pursuant to section 355(a)."</p> <p>(f) "The Secretary may by regulation (1) require devices and certain types of electronic products, to which there are applicable standards prescribed under this Subpart and the retail prices of such devices not less than \$50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes of this Act; and (2) require manufacturers to preserve such information until such time as the Secretary or any of his duly authorized representatives, or the copying of such records, or the carrying out of inspection, as authorized pursuant to section 303A</p> <p>(3) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the marketing, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession to any other State or possession. The purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, investigation, quarantine, sanitation, pest control, decontamination of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to humans and the measures, as in his judgment, may be necessary."</p> <p>(4) "Other officers or employees making an inspection (1) in the case of any such inspection of a factory, consulting laboratory, or other establishment, and the premises, the officer or employee making the inspection shall have access to and to copy and to verify any thing in violation of this Act or which may be subject to inspection under this Act; and (2) in the case of any such inspection of a factory, consulting laboratory, or other establishment, and the premises, the officer or employee making the inspection shall have access to and to copy and to verify such records."</p> <p>(5) "Every person required under this Act, section 414, or section 415 to maintain records, and every person who in charge or custody of such records, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and to verify such records."</p> <p>(6) "An accredited person described in paragraph (3) shall maintain records concerning the training and qualifications of the person and the employees of the person, the circumstances used by the person for and in confidential information, the compensation arrangements made by the person, and the practices used by the person in identifying and avoid conflicts of interest upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, and to copy and to verify, such records."</p> <p>(7) "In the case of any new animal drug for which an approval of an application pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience (including experience data) as authorized under subsection (a)(4)(A), and other data on information, received or otherwise obtained by such applicant with respect to such drug, or with respect to data, records bearing on or containing such data, as the Secretary may by general regulation or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine or facilitate a determination whether the drug or may be found for having subsection (a) or subsection (b) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request by the persons to whom such regulation or order is applicable, of available information received or otherwise obtained by the Secretary."</p> <p>(8) "Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and to verify such records."</p> <p>(9) "Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:</p> <p>Part F - Licensing - Biological Products and Clinical Laboratories and"</p> <p>(10) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during a reasonable time of entry and record any establishment for the inspection or manufacture and preparation."</p> <p>(Continued on Page 3)</p>	

of any virus, serum, toxin, antitoxin, vaccine, blood component, or derivative, allergenic product, or other product intended for human use, in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - Licensing - Biological Products and Clinical Laboratories and"

Sec. 263A (a) "The Secretary may by regulation (1) require devices and certain types of electronic products, to which there are applicable standards prescribed under this Subpart and the retail prices of such devices not less than \$50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes of this Act; and (2) require manufacturers to preserve such information until such time as the Secretary or any of his duly authorized representatives, or the copying of such records, or the carrying out of inspection, as authorized pursuant to section 303A

(3) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the marketing, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession to any other State or possession. The purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, investigation, quarantine, sanitation, pest control, decontamination of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to humans and the measures, as in his judgment, may be necessary."

(4) "Other officers or employees making an inspection (1) in the case of any such inspection of a factory, consulting laboratory, or other establishment, and the premises, the officer or employee making the inspection shall have access to and to copy and to verify any thing in violation of this Act or which may be subject to inspection under this Act; and (2) in the case of any such inspection of a factory, consulting laboratory, or other establishment, and the premises, the officer or employee making the inspection shall have access to and to copy and to verify such records."

(5) "Every person required under this section to maintain records, and every person who in charge or custody of such records, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and to verify such records."

(6) "An accredited person described in paragraph (3) shall maintain records concerning the training and qualifications of the person and the employees of the person, the circumstances used by the person for and in confidential information, the compensation arrangements made by the person, and the practices used by the person in identifying and avoid conflicts of interest upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, and to copy and to verify, such records."

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Part F - Licensing - Biological Products and Clinical Laboratories and"

(10) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during a reasonable time of entry and record any establishment for the inspection or manufacture and preparation."

(Continued on Page 3)

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(Continued on Page 3)

Copy Of FDA Form 482

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO.	
2. NAME AND TITLE OF INDIVIDUAL		3. DATE	
4. FIRM NAME		5. HOUR	a.m.
6. NUMBER AND STREET			p.m.
7. CITY AND STATE & ZIP CODE		8. PHONE NO. & AREA CODE	
<p>Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)]¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]²</p> <p>As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-5247. The website address is www.sba.gov/ombudsman</p> <p>FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 798-8530 or by email at ombuds@fda.gov.</p> <p>For industry information, go to www.fda.gov/oc/industry.</p>			
9. SIGNATURE(S) (Food and Drug Administration Employee(s))		10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))	
<p>¹ Applicable portions of Section 704 and Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below.</p> <p>Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of a foreign manufacturer (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or introduces foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable</p>		<p>belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(c). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (Continued on Reverse)</p>	

“**Sec. 704(a)(1)** For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, **tobacco products**, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.”

What If A Retailer Is Inspected But There Were No Violations Observed?

- FDA does not send a letter or email
- On its website, FDA posts the names of retailers who were inspected whether or not a violation was observed.
- The list is contained in a searchable database that is updated monthly and found here:

www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm

- The search screen gives you the option of looking for just retailers that have no violations observed



Compliance Check Inspections of Tobacco Product Retailer

Search Inspection Decisions		Help
Retailer Name	<input type="text"/>	Decision Type <input type="text" value="All"/>
City	<input type="text"/>	Decision Date <input type="text"/> to <input type="text"/>
State	<input type="text" value="All"/>	Zip <input type="text"/>
Date Format: mm/dd/yyyy. For example: 05/01/2011		
<input type="button" value="Search"/> <input type="button" value="Clear"/>		Records per Report Page <input type="text" value="10"/>
Export All Data to Excel		

Includes Inspection Decisions Through: 07/29/2011

Date Last Updated: 08/16/2011

What If A Retailer Is Inspected And There Are Violations Observed?

- Although not required, the first time an FDA tobacco compliance check inspection reveals a violation, FDA intends to issue a Warning Letter.
- A Warning Letter is an agency advisory action that is used to achieve voluntary compliance with the TCA and to establish prior notice. It is not the final agency action.

What If A Retailer Is Inspected And There Are Violations Observed?

- The Warning Letter will contain a description of each violation observed
- It is FDA's practice to give firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action
- FDA requests a response to the Warning Letter within 15 days
- A Civil Money Penalty is an example of an enforcement action that would be taken following the issuance of a Warning Letter if additional violations are observed during a subsequent compliance check inspection.

Will A Retailer Know That FDA Has Issued A Warning Letter To Them?

- Warning Letters are sent to the retail establishment by tracked mail, currently UPS.
- The Warning Letter will be sent to the address we have on record for the retail establishment.
- A copy of the Warning Letter may also be sent to the legal entity or owner of the retail establishment, if their address is different than that of the retail establishment.

Will A Retailer Know That FDA Has Issued A Warning Letter To Them?

- Warning Letters are also posted on the FDA website, located at:
<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/Tobacco/default.htm>
- Anyone can sign up to receive email updates when new tobacco compliance check Warning Letters are posted to the above portion of the FDA website.



U.S. Food and Drug Administration

Email Updates

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We have a strict [privacy policy](#).

Email Address



Your contact information is used to deliver requested updates or to access your subscriber preferences.

What Will The Warning Letter Include?

- The date the Warning Letter was issued
- The date FDA inspected the retailer
- The location where the inspection occurred
- The inspection reference number – which should be used in any future correspondence with FDA



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

Date of Warning Letter

WARNING LETTER

XXX XX, 20XX

Location of Inspection

VIA UPS

XYZ Cigarette Store
Attn: Site Manager
123 Anywhere Street
City, State, Zip Code

Reference Number

Date of Inspection

Re: Reference Number: XXXXXXXXXXXX

Dear Sir or Madam:

On XXX, XX, 20XX, an inspector representing the United States Food and Drug Administration (FDA) completed a compliance check inspection of your establishment located at **123 Anywhere Street, City, State, Zip Code**. Your establishment sells cigarettes and/or smokeless tobacco products. The sale, distribution, advertising, and promotion of your tobacco products must comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, found at Title 21, Code of Federal Regulations (C.F.R.), Part 1140. You are legally responsible for complying with these regulations and for ensuring that your employees comply with these regulations.

What Will The Warning Letter Include?

- An explanation that your tobacco products are **misbranded*** under the FD&C Act

* Once a product is considered misbranded FDA can take enforcement action against the party who causes the misbranding or any party who further distributes the misbranded product. Misbranding of a tobacco product is prohibited under the FD&C Act.

- The particular violation(s) FDA inspectors observed and an explanation of the evidence used to support the violation(s).

“ Misbranded ”

This compliance check inspection revealed that your tobacco products are **misbranded** within the meaning of section 903(a)(7)(B) of the FD&C Act, 21 U.S.C. § 387c(a)(7)(B), in that they are sold or distributed in violation of 21 C.F.R. Part 1140. The violations identified at your establishment include, but are not limited to, the following:

1. Sale of cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a).

For example, you or one of your employees sold a package of XYZ Cigarettes to a minor on XXX, XX, 20XX.

2. Failure to verify by means of photographic identification, containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age, as required by 21 C.F.R. § 1140.14(b)(1). No such verification is required for any person over the age of 26, as per 21 C.F.R. § 1140.14(b)(2).

For example, you or one of your employees sold a package of XYZ Cigarettes to a minor on XXX XX, 20XX and failed to verify by means of photographic identification that the minor was 18 years of age or older.

Violation(s) Observed

Examples Of Violations In Warning Letters

- Sale of cigarettes, smokeless tobacco, or loose cigarette tobacco to a person younger than 18 years of age. (21 C.F.R. § 1140.14(a)).
- Failing to verify by means of photographic identification, containing the bearer's date of birth, that no person purchasing cigarettes, smokeless tobacco, or loose cigarette tobacco is younger than 18 years of age. (21 C.F.R. § 1140.14(b)(1)).*

*No such verification is required for any person over the age of 26. (21 C.F.R. § 1140.14(b)(2)).

If a retailer does not verify by photo that the purchaser is 18 years of age or older and also sells the purchaser cigarettes, smokeless tobacco, or loose cigarette tobacco, both separate violations will be listed on their warning letter.

Examples Of Violations In Warning Letters

- Failing to sell cigarettes, smokeless tobacco, or loose cigarette tobacco in a direct, face-to-face exchange between the retailer and consumer. (21 C.F.R. § 1140.16(c)(1)).

Selling cigarettes through vending machines and self-service displays without ensuring that no person younger than 18 years of age is present or permitted to enter, at any time. (21 C.F.R. § 1140.16(c)(2)(ii)).

- Failing to ensure that all violative self-service displays, advertising, labeling, and other items that are located in your establishment are removed or are brought into compliance with the requirements of 21 C.F.R. Part 1140. (21 C.F.R. § 1140.14(e)).

Excerpt from a Warning Letter

upon asking for a tobacco product, your store clerk instructed a minor to go to checkout number one, where the tobacco products were located, and to get the tobacco products himself. The minor proceeded to checkout number one and directly accessed a tobacco product to purchase. There was no store employee working behind checkout number one

What Will The Warning Letter Include?

- A statement directing the retailer to cease the violation(s) and to correct the violation(s).
- A reminder that failure to comply may result in FDA taking further regulatory action without notice.
- A request that the retailer submit a written response within fifteen (15) working days of receiving the Warning Letter.

“Immediately correct the violation”

You should **immediately correct the violation(s)** by ceasing the violative marketing, sale, and/or distribution of tobacco products to consumers at your establishment. **Failure to correct the violation(s) may result in regulatory action being initiated by the FDA without further notice.** These actions may include, but are not limited to, a civil money penalty, no-tobacco-sale order, seizure, and/or injunction.

Failure to comply. . .

Please submit a written response to this letter within 15 working days from the date you receive this letter, describing your intent to comply with this request and explaining your plan for discontinuing the violative marketing, sale, and/or distribution of your tobacco products. As part of your response, please include a phone number and an email address at which we may contact you and make note of any discrepancies in the contact information related to your business or corporate entity.

Submit written response within 15 days

What Will The Warning Letter Include?

- The address where the retailer should send their response.
- A reminder that the violation(s) identified in the Warning Letter are not necessarily an exhaustive list.
- Contact information for the FDA, Center for Tobacco Products.

Your response should specify the reference number identified at the beginning of the letter and be addressed to:

SP-WL Response
FDA Center for Tobacco Products
9200 Corporate Boulevard
c/o Document Control Center
Rockville, Maryland 20850

Where to send response
Include Reference Number

The violation(s) discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your tobacco products comply with the applicable provisions of the FD&C Act, as amended by the Tobacco Control Act and applicable regulations.

not necessarily constitute an
exhaustive list

If you have any questions about the content of this letter, please contact _____.

Contact Information for
questions about the
Warning Letter

What Should A Retailer Do If They Receive A Warning letter?

- Review the letter carefully to see what charges are listed.
- Contact CTP if you are confused.
- Phone and email provided in Warning Letter
- Respond to the letter in writing (or email).
 - Remember to use the reference number listed in the letter.

What Should A Retailer Include In Their Response?

- A description of the retailer's intent to stop the violation(s).
- An explanation of the retailer's plan to discontinue the violation(s) and prevent future violations.
- The retailer's current telephone number and email address.

What Happens After A Retailer Responds To A Warning Letter?

- FDA will send a reply to your response letter closing out the case.
 - This reply will contain a summary of the retailer's response to the Warning Letter.
- FDA will conduct a follow-up compliance check inspection at that establishment without further notice to the retailer.
- If violations are found during a follow-up compliance check inspection at that retail outlet, FDA intends to seek civil money penalties.

Contact Information

For questions about the material in this presentation, please contact our Office of Small Business Assistance at:

SmallBiz.Tobacco@fda.hhs.gov

or call 1-877-CTP-1373 (1-877-287-1373)

Monday–Friday, 9:00 a.m. – 4:00 p.m. EDT.