WHAT A BRICK AND MORTAR RETAILER SHOULD DO AFTER RECEIVING A WARNING LETTER

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Office of Compliance and Enforcement
Center for Tobacco Products
FDA

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AGENDA

- What is a Warning Letter?
- What is a Compliance Check Inspection Notification?
- What does a Warning Letter include?
- What should I do if I receive a Warning Letter?
- How do I respond to a Warning Letter?
- What happens next?
- FDA resources for retailers
Brick and Mortar Retailers
- This webinar provides information to tobacco product brick and mortar retailers about Warning Letters that FDA may issue as a result of a tobacco retailer inspection.

- This webinar does not cover Warning Letters FDA may issue to other regulated entities, including online tobacco product retailers.

- For more information about online tobacco retailer enforcement please visit our website at: https://www.fda.gov/tobacco-products/compliance-enforcement-training.
WHAT IS A WARNING LETTER?

• A Warning Letter is the Agency’s advisory action that alerts a retailer, and provides notice, that their establishment is not in compliance with Federal laws and regulations regarding the sale and distribution of regulated tobacco products.

• The first time FDA finds violation(s) during a tobacco retailer inspection, FDA typically issues a Warning Letter.

• The Warning Letter prompts the retailer to address current violations and provides information for the retailer to help prevent future violations.
What is a Compliance Check Inspection Notification?

- If a sale to an underage purchaser is documented during a tobacco retailer inspection, a Compliance Check Inspection Notification (CCI) is typically mailed to the retail establishment.

- **The CCI is not a Warning Letter.** The FDA sends CCI notices as a courtesy to retailers shortly after a potential violation(s) for selling tobacco products to a person under 21 years of age.

- The CCI provides the retailer with detailed information about the inspection, including a photo of the establishment taken at the time of the inspection, the date and time of the inspection, and a description of the clerk (if available) who made the sale.

- No response is required for a CCI. However, if the establishment identified in the CCI is not your establishment, you should contact FDA.
WHAT DOES THE WARNING LETTER INCLUDE?

- FDA will review the evidence obtained during the inspection at the retail establishment to determine whether there was a violation of Federal laws and regulations.

- If FDA determines a violation occurred and you receive a Warning Letter, the Warning Letter will include the following information:
  - The inspection date
  - The approximate time of inspection
  - Description of the specific violation(s) observed
  - Relevant Federal tobacco laws and regulations
  - Information on how to submit a written response
  - Statement that violations listed in the Warning Letter may not be a complete list of violations at the establishment
  - Reminder to comply with all applicable laws and regulations
WHAT SHOULD I DO IF I RECEIVE A WARNING LETTER?

• After receiving a Warning Letter, you should:
  – Carefully review the listed violation(s)
  – Review the Warning Letter to ensure the establishment information is correct
    ▪ If the establishment information is incorrect, you should notify FDA
  – Respond to the Warning Letter in writing within fifteen (15) working days of receipt
  – Take action to address the listed violations in order to ensure future compliance
  – Preserve any evidence or information relevant to this Warning Letter in the event FDA takes regulatory action at a later date
HOW DO I RESPOND TO A WARNING LETTER?

• Directions on how to respond will be included in the Warning Letter. These directions request your response within 15 working days by either:
  • **E-mail** to: CTP-WL@fda.hhs.gov (scanned responses are acceptable)
  • **Phone**: contact the Center for Tobacco Products at 1-877-CTP-1373, or
  • **Mail** to:
    Food and Drug Administration
    Center for Tobacco Products
    Document Control Center
    Building 71, Room G335
    10903 New Hampshire Avenue
    Silver Spring, MD 20993-0002

• Your Warning Letter Response should include:
  • Your current contact information, including address, telephone number, and e-mail address.
  • The reference number listed at the top of your Warning Letter.
  • An explanation of the steps you will take to address the violation(s) and prevent future violations (e.g., retrain your employees, remove the problematic items, etc.).
If your Warning Letter comes with a voluntary Warning Letter response document, you may use it to respond or you can submit your own written response.

- A voluntary Warning Letter response document may be sent via mail or e-mail to FDA.
- Voluntary Warning Letter response document example:

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Please check all that apply and sign below.

☐ I understand that under Federal Law, a tobacco retailer must NOT sell cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco or covered tobacco products such as electronic nicotine delivery systems (ENDS), e-liquids, cigars, pipe tobacco, hookah or dissolvable nicotine products to a person younger than 21 years of age.

☐ I understand that under Federal Law, a tobacco retailer MUST check a photographic identification (that includes a date of birth) for any person under the age of 27 who attempts to purchase cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco or covered tobacco products such as electronic nicotine delivery systems (ENDS), e-liquids, cigars, pipe tobacco, hookah or dissolvable nicotine products.

I understand that I am responsible for preventing violations in the future. My plan for correcting the violations listed in the Warning Letter includes the following (Please check any actions that you plan to take to prevent future violations):

☐ Clearly displaying materials that inform customers and employees of the underage sale restrictions and age verification requirements

☐ Placing at the sales counter a calendar that displays the minimum date of birth required to purchase tobacco
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WILL FDA CONFIRM RECEIPT OF MY WARNING LETTER RESPONSE?

• No. Generally FDA will NOT contact you after receipt of a Warning Letter response.

• FDA may contact you if additional information or clarification is needed regarding your response.
WHAT HAPPENS NEXT?

• FDA will conduct follow-up inspections at your establishment. These inspections will not be scheduled or pre-announced.

• You must continue to comply with all applicable tobacco laws and regulations.

• If violations are observed during a follow-up inspection it may result in FDA taking additional enforcement action without notice, including a Civil Money Penalty or No-Tobacco-Sale Order.

• Inspection results will be added to our Compliance Check Inspection database, which is updated monthly.
  – To access this database, go to: https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm
For additional questions, you can contact FDA:

- CTP General E-mail: AskCTP@fda.hhs.gov
- Call: 1-877-287-1373 (9am EST-4pm EST)
- Small Business E-mail: SmallBiz.Tobacco@fda.hhs.gov
FDA RESOURCES FOR RETAILERS

• Retail Sales of Tobacco Products
  https://www.fda.gov/tobacco-products/compliance-enforcement-training/retail-sales-tobacco-products

• Summary of the Federal Rules for Selling Tobacco Products

• “This is Our Watch” Campaign for Retailers
  https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch

• Social Media Links (E.g.: Twitter, Facebook, YouTube)
  https://www.fda.gov/tobacco-products/contact-ctp/connect-ctp

• Sign up for CTP E-mail updates
  www.fda.gov/tobacco-products/ctp-newsroom