

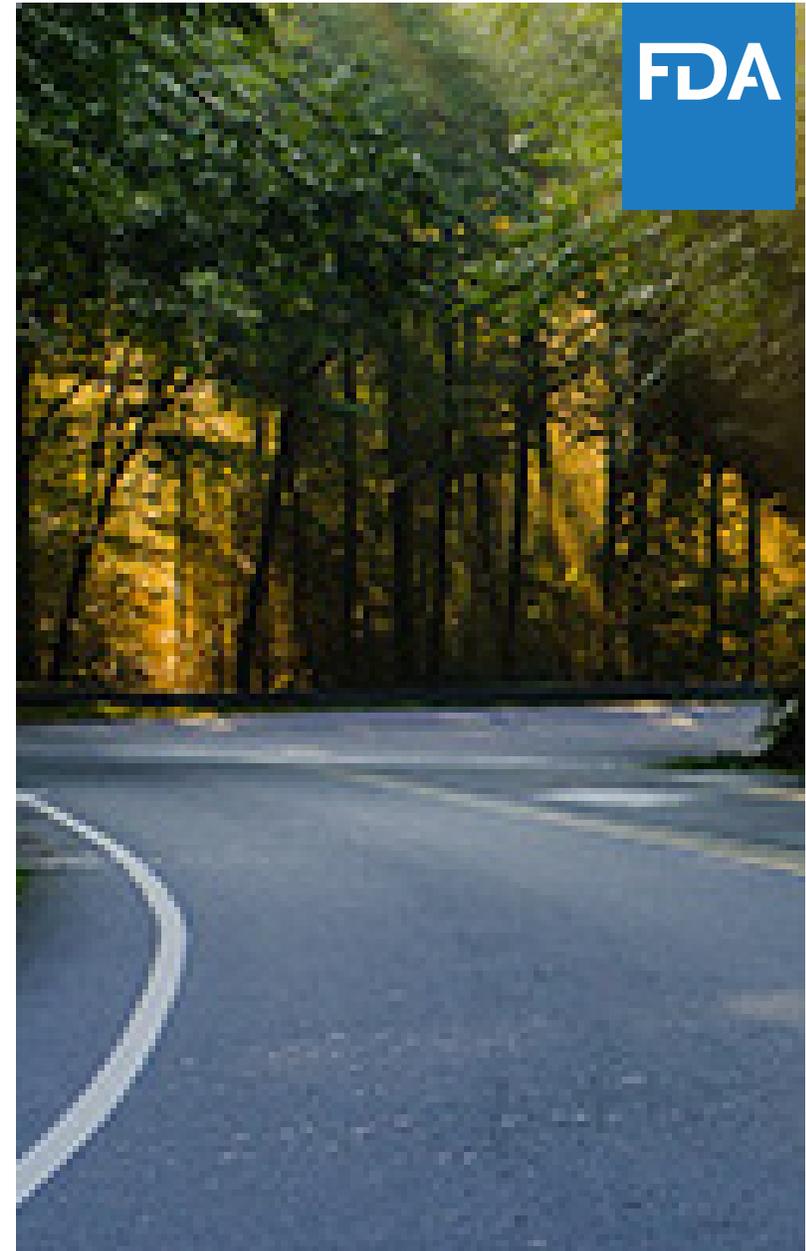
# WHAT A BRICK AND MORTAR RETAILER SHOULD DO AFTER RECEIVING A WARNING LETTER

*Presented by:*  
*Office of Compliance and Enforcement*  
*Center for Tobacco Products*  
*FDA*

*Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.*

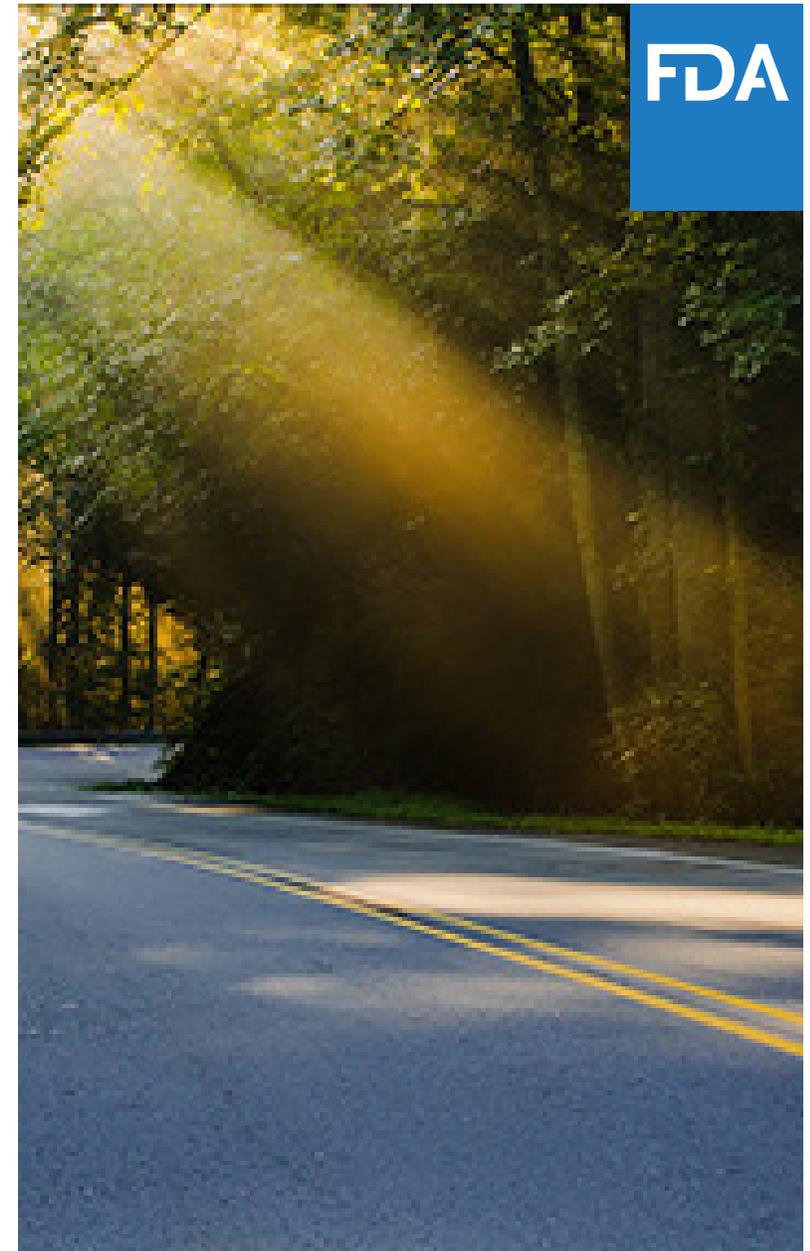
# AGENDA

- 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



# AGENDA NOTE

- 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](mailto: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.).

# HOW DO I RESPOND TO A WARNING LETTER?

- 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:

*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

# 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.
  - More detailed information available at: [www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores](http://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores)
- 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/oc/inspections/oc\\_insp\\_searching.cfm](https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm)

# WHAT IS THE BEST WAY TO CONTACT FDA WITH ADDITIONAL QUESTIONS?

- For additional questions, you can contact FDA:
  - CTP General E-mail: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov)
  - Call: 1-877-287-1373 (9am EST-4pm EST)
  - Small Business E-mail: [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov)

- 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  
<https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores>
- “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](http://www.fda.gov/tobacco-products/ctp-newsroom)

# CONCLUSION