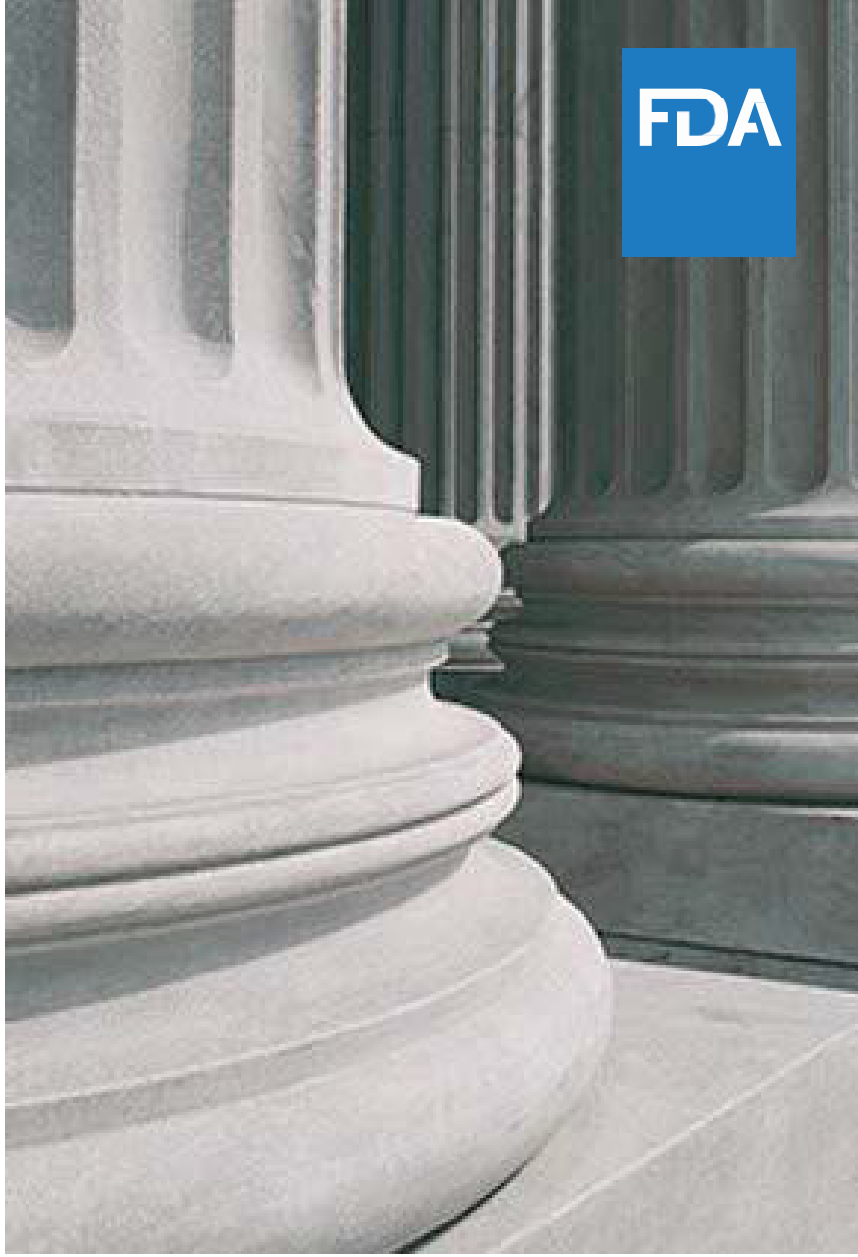
WHAT A MANUFACTURER OR VAPE SHOP OWNER SHOULD DO AFTER RECEIVING A WARNING LETTER



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

AGENDA

- Responding to a Warning Letter
- Resources

RESPONDING TO A WARNING LETTER

RESPONDING TO A WARNING LETTER

Carefully read the letter and address the issues raised. The written response should be directed to the address listed in the Warning Letter and should include:

- Current contact information, including address, telephone number, and e-mail address
- The reference number listed at the bottom of the Warning Letter

RESPONDING TO A WARNING LETTER

Warning Letter responses may include:

- Each step taken or that will be taken to completely correct the current violations and prevent similar violations
- The precise time it will take to make any corrections
- Any reason the corrective action cannot be completed within a timely manner (if applicable)
- Any documentation necessary to show that corrective actions have been made. This should also include documentation demonstrating the destruction, disposal or reconditioning of all violative products, where applicable

See Chapter 4 of the Regulatory Procedures Manual Feb 2022 for more information.

RESPONDING TO A WARNING LETTER

- If you have any questions about the content of a Warning Letter please contact CTPCompliance@fda.hhs.gov
- If you believe your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration
- It is always the manufacturer's responsibility to ensure that it complies with each applicable provision of the FD&C Act and FDA's implementing regulations. Neither responding nor failing to respond to a Warning Letter absolves a manufacturer of that continuing responsibility.

POST WARNING LETTER ACTIONS

- FDA may contact you if additional information or clarification is needed regarding your response
- FDA will typically conduct follow-up inspections at your establishment.
- If continued violations are observed during a follow-up inspection, it may result in FDA taking enforcement action without notice, including, but not limited to, civil money penalties, seizure, or injunction.

QUESTIONS

- If you have any questions about the content of a Warning Letter please contact CTPCompliance@fda.hhs.gov
- General inquiries can be sent to ASKCTP@fda.hhs.gov or by calling 1-877-287-1373
- For all small business questions contact the Office of Small Business Assistance at Smallbiz.tobacco@fda.hhs.gov
- The CTP Ombudsman's Office provides a "safe space" for stakeholders to voice their questions, concerns, or complaints about FDA regulation of tobacco products, and can be reached at CTP Ombudsman | FDA

RESOURCES

RESOURCES AND CONTACTS

CTP Website available at:
http://www.fda.gov/TobaccoProducts/default.htm

For General Inquiries contact via email or phone:
AskCTP@fda.hhs.gov 1-877-CTP (287)-1373

Inquiries from small businesses:
Smallbiz.tobacco@fda.hhs.gov

CTP Ombudsman | FDA

Sign up for "CTP News" and "CTP *Connect*" to receive CTP's email updates.

ADDITIONAL RESOURCES

Additional information on the pathways to market a new tobacco product can be found at the Market and Distribute a Tobacco Product page of the FDA website.

ADDITIONAL RESOURCES

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments

Registration and Listing mailbox:
CTPRegistrationandListing@fda.hhs.gov

The Tobacco Registration and Product Listing Updates Webinar

ADDITIONAL RESOURCES

Provision(s)	Resources and References
Premarket tobacco product authorization required for tobacco products unless: • FDA has issued a substantial equivalence (SE) order for the tobacco product • FDA has granted a substantial equivalence exemption request • The product was on the market as of February 15, 2007, and has remained unchanged since then (Pre-Existing). **(§§ 910 and 905(j) of the FD&C Act)**	Section 905 of the FD&C Act Section 910 of the FD&C Act FDA Guidance for Industry: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

ADDITIONAL RESOURCES

Additional information can be found below:

FDA Tobacco Compliance Webinars

FDA Regulatory Procedures Manual

CTP Regulations

CTP Guidance Documents