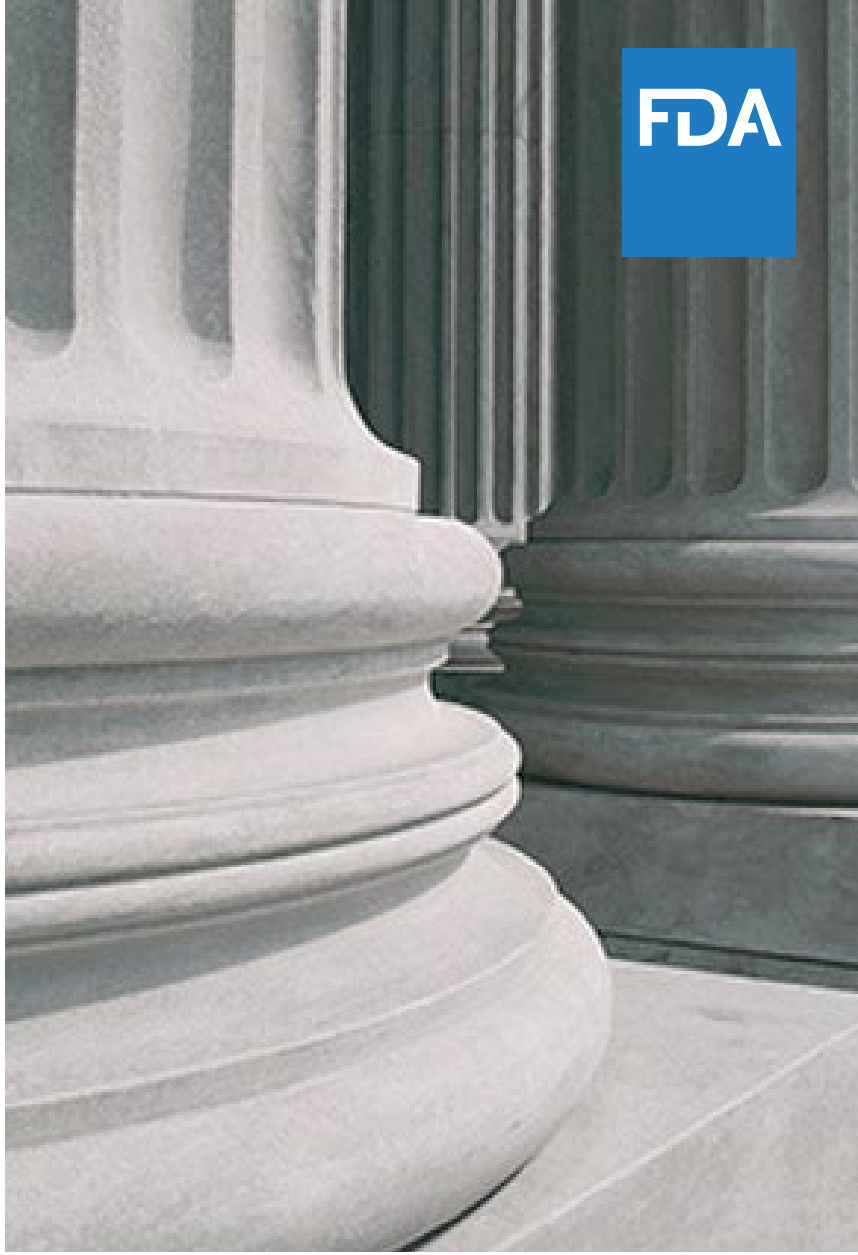
OVERVIEW OF WARNING LETTERS FOR ONLINE RETAILERS



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AGENDA

- Overview of Internet and Publication Surveillance
- Warning Letters
- Examples of Violations
- Responding to Warning Letters

FDA'S REGULATION OF TOBACCO PRODUCTS

- The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and any other tobacco products that the agency, through regulation, deems to be subject to its tobacco product authorities (Section 901(b) of the FD&C Act [21 U.S.C. 387a]).

- The Final Deeming rule became effective on August 8, 2016, which gave FDA authority over all products that meet the definition of a tobacco product under section 201(rr) of the FD&C Act, including components and parts, **except** accessories of newly deemed tobacco products, subject to FDA's tobacco product authorities in chapter IX of the FD&C Act and its implementing regulations.

- On March 15, 2022, the President signed legislation to amend the FD&C Act to extend FDA's jurisdiction to products "containing nicotine from any source," not just nicotine derived from tobacco.

FDA REGULATED TOBACCO PRODUCTS

Examples of Tobacco Products Regulated Before Deeming Rule	Examples of Regulated Tobacco Products Under the Deeming Rule
• Cigarettes • Cigarette tobacco • Roll-Your-Own tobacco • Smokeless tobacco *This includes the components, parts, and accessories of these products.*	• ENDS* • Pipe tobacco • Cigars • Hookah/Waterpipe tobacco • E-liquid • Dissolvable tobacco products not already regulated by FDA • Future tobacco products *This includes the components and parts of these products, but not their accessories.*

***ENDS = Electronic Nicotine Delivery System (example: e-cigarette, e-hookah, vape pens)**

For more information, we encourage you to visit our website: https://www.fda.gov/tobacco-products/products-guidance-regulations/products-ingredients-components.

COMPONENTS OR PARTS

Component or Part is defined as any software or assembly of materials intended or reasonably expected:

- To alter or affect the tobacco product's performance, composition, constituents or characteristics; or
- To be used with or for the human consumption of a tobacco product.

Component or part excludes anything that is an accessory of a tobacco product. Some examples of components and parts include cigar tobacco filler, filters, or wrappers, and batteries for ENDS (21 C.F.R. § 1100.3).

CTP'S INTERNET AND PUBLICATION SURVEILLANCE

- CTP conducts routine surveillance of sales, distribution, marketing, and advertising activities related to regulated tobacco products on the Internet, including social media, and in publications.

- CTP has issued Warning Letters to tobacco product manufacturers, importers, distributors, and retailers for violations of the FD&C Act and its implementing regulations.

- For more information, we encourage you to visit our website: https://www.fda.gov/tobacco-products/compliance-enforcement-training/retail-sales-tobacco-products

INTERNET AND PUBLICATION SURVEILLANCE

- For example, Warning Letters have been issued to online retailers for the following violations:
  - Selling tobacco products to individuals under the federal minimum age of sale.
  - Offering for sale and/or advertising smokeless tobacco products, cigarette tobacco, roll-your-own tobacco, and covered tobacco products (other than cigars and pipe tobacco) without the required warning statement.
  - Offering for sale new tobacco products without required marketing authorization, including ENDS products that were marketed and/or targeted to youth.
  - Selling or distributing, in interstate commerce, tobacco products as modified risk tobacco products without an FDA order in effect.

WARNING LETTERS

Warning Letter

- Generally, FDA issues Warning Letters for violations of regulatory significance.
- A Warning Letter is an agency advisory action that is used to notify regulated industry of violations and achieve voluntary compliance with the FD&C Act and its implementing regulations. It is not a final agency action.
- A Warning Letter contains a description of cited violations and requests a response from a firm within 15 working days of the Warning Letter's receipt. The response should describe corrective actions, including dates the violations were corrected, and a plan for maintaining compliance with the FD&C Act.

WARNING LETTERS

- It is regulated industry's responsibility to ensure that their respective tobacco products and all related labeling and advertising on their respective websites, on any other websites (including e-commerce, social networking, or search engine websites), as well as any other media in which they advertise, and in any retail establishments comply with the FD&C Act and its implementing regulations.

- Failure to ensure full compliance with the FD&C Act may result in FDA taking regulatory or legal action, including, but not limited to, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction.

WARNING LETTERS

Warning Letters are also posted on the FDA website

- Internet and Publication Surveillance: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

- State Retailer Compliance Check Inspections: https://timp-ccid.fda.gov

EXAMPLES OF VIOLATIONS

- Selling tobacco products to individuals under the federal minimum age of sale.
- Offering for sale and/or advertising smokeless tobacco, cigarette tobacco, roll-your-own tobacco, and covered tobacco products (other than cigars and pipe tobacco) without the required warning statement.
- Offering for sale new tobacco products without required marketing authorization, including ENDS products that were marketed and/or targeted youth.
- Selling or distributing, in interstate commerce, tobacco products as modified risk tobacco products without an FDA order in effect.

SALES TO UNDERAGE INDIVIDUALS

- A retailer is defined as any person who sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted.
- Effective December 20, 2019, an amendment to the FD&C Act raised the minimum age of sale of tobacco products from age 18 to 21 years. Under section 903(a)(7)(B) of the FD&C Act, tobacco products are misbranded if sold or distributed to any person younger than 21 years of age.
- FDA encourages online retailers to use adequate means of age and identity verification to prevent sales of cigarettes, smokeless tobacco, or covered tobacco products online to individuals under the age of 21 years. An example of age verification may include using an independent age and identity verification service that compares customer information against independent, competent, and reliable data sources, such as public records, to prevent the sale to individuals who are under 21 years.

REQUIRED WARNING STATEMENT REGARDING ADDICTIVENESS OF NICOTINE

WARNING: This product contains nicotine.
Nicotine is an addictive chemical.

- The required nicotine warning statement must appear on packages and advertisements for covered tobacco products (except cigars and pipe tobacco) and roll-your-own/cigarette tobacco products.

- This required warning statement must also meet certain requirements, with respect to font, text, size, placement and formatting of the warning statement.

WARNING STATEMENTS FOR CIGARS AND PIPE TOBACCO

- The United States District Court for the District of Columbia issued an order vacating the health warning requirements for cigars and pipe tobacco set forth in 21 CFR §§ 1143.3 and 1143.5 and remanded the Final Deeming Rule's warning requirements for cigars and pipe tobacco back to the Agency. See Order, *Cigar Ass'n of Am. v. U.S. Food & Drug Admin*., No. 1:16-cv-01460 (D.D.C. September 11, 2020).

- Although the requirement has been vacated, cigar and pipe tobacco firms may choose to voluntarily comply with these health warning provisions.

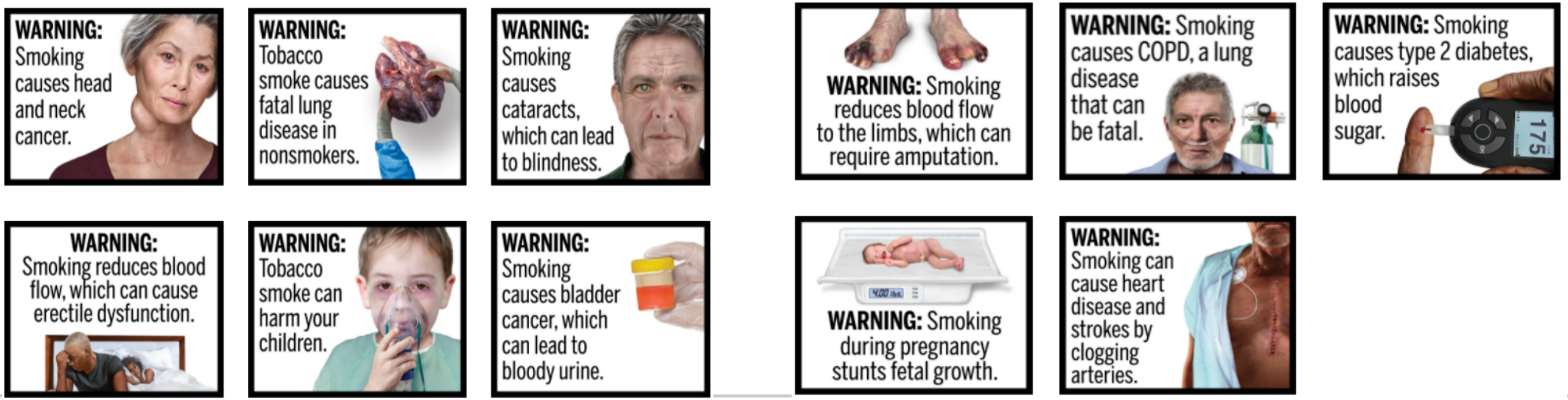
REQUIRED WARNING STATEMENTS FOR SMOKELESS TOBACCO

- Smokeless tobacco packages and advertisements must bear one of the four following warning label statements in accordance with an FDA-approved plan:
  - **WARNING**: This product can cause mouth cancer.
  - **WARNING**: This product can cause gum disease and tooth loss.
  - **WARNING**: This product is not a safe alternative to cigarettes.
  - **WARNING**: Smokeless tobacco is addictive.
- These required warning statements must also meet certain requirements, with respect to font, text, size, placement and formatting of the warning statements on the package labels and advertisements.
- Lack of the required smokeless tobacco product warning label statements renders the product misbranded under sections 903(a)(1) and/or 903(a)(7)(A) of the FD&C Act.

WARNING STATEMENTS FOR CIGARETTES

Cigarettes: In March 2020, FDA finalized the "Required Warnings for Cigarette Packages and Advertisements" rule, establishing 11 new cigarette health warnings

- On Dec. 7, 2022, the U.S. District Court for the Eastern District of Texas issued an order in the case of R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al., No. 6:20-cv-00176, vacating the "Required Warnings for Cigarette Packages and Advertisements" rule. Currently, FDA is not recommending that entities submit cigarette plans. If a firm has already submitted a plan, no further action is needed at this time. FDA will provide further updates regarding submission of cigarette plans as they are available.



TOBACCO PRODUCTS WITHOUT REQUIRED MARKETING AUTHORIZATION

- All new tobacco products, including ENDS products, must receive premarket authorization from FDA to be legally marketed.
- In addition, premarket applications for all new tobacco products on the market as of August 8, 2016, including ENDS, were due to FDA by the court-ordered September 9, 2020, deadline.
- New tobacco products marketed without required marketing authorization risk FDA enforcement (except for “premium cigars”).
  - For more information, we encourage you to visit our website: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders.

NON-TOBACCO NICOTINE PRODUCTS

- As of April 14, 2022, manufacturers, distributors, importers and retailers of tobacco products containing non-tobacco nicotine (NTN) —that is, nicotine not made or derived from tobacco, such as synthetic nicotine—must ensure compliance with applicable requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, such as:
    - Not selling these products to persons under 21 years of age (both in-person and online);
    - Not marketing these products as modified risk tobacco products without FDA's authorization; and
    - Not distributing free samples of these products.
- Manufacturers of NTN products who wish to market their products are required to submit a premarket application and obtain FDA authorization to market their product. All NTN products on the market without premarket authorization are subject to FDA enforcement.

WARNING LETTERS

FDA has issued warning letters to companies for marketing unauthorized ENDS products that imitate foods such as Popsicles; feature youth-appealing characters from the TV show “Baby Bus;” or are designed to look like toys and youth-appealing electronics like glow sticks and walkie-talkies.

E-Cigarette

Popsicle

E-Cigarette

Cartoon

E-Cigarette

Toy

E-Cigarette

Toy

WARNING LETTERS

- FDA has issued over 250 warning letters to companies who manufacture and operate websites selling ENDS products, including ENDS products made with non-tobacco nicotine, also known as NTN, that lack premarket authorization, advising them that selling these products is illegal, and therefore cannot be sold or distributed in the U.S.
  - For more information, we encourage you to visit our website: https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products

MODIFIED RISK TOBACCO PRODUCTS

Section 911 of the FD&C Act provides that:

- No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an order in effect, issued pursuant to section 911(g) of the FD&C Act. (Section 911(a) of the FD&C Act).

- Modified Risk Tobacco Product (MRTP) means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products (Section 911(b)(1) of the FD&C Act).

WARNING LETTERS

FDA has issued Warning Letters to firms for selling or distributing ENDS products that were labeled or advertised as presenting a lower risk of tobacco-related disease, being less harmful than one or more other commercially marketed tobacco products, or having a reduced level of exposure to a substance, without a marketing order in effect, in violation of section 911 of the FD&C Act. For example:

- “Vaping is used as (sic) safer and healthier alternative to smoking.”
- “The Rosy has two separate departments for the battery and juice, which certain physicians believe decreases turbulence and consumption of harmful metals, including aluminum, lithium, cranium [sic], and others.”

WARNING LETTER RESPONSES

- Once the Warning Letter is received, the firm should take prompt action to correct the violation(s) cited in the letter.
- A Warning Letter contains a description of cited violations and requests a response from a firm within 15 working days of the Warning Letter's receipt.
- The violation(s) cited in the Warning Letter are not intended to be an all-inclusive statement of violations associated with their tobacco products and marketing activities.

WARNING LETTER RESPONSES

What to include in your response:

- Describe your plan to mitigate and correct the violation(s) identified in the Warning Letter as well as any additional corrective actions taken.
- Include dates which corrective actions were taken.
- Describe your plan for maintaining compliance with the FD&C Act.

The response also provides an opportunity to explain why you believe your products are not in violation of the FD&C Act and its implementing regulations.

Failure to ensure full compliance with the FD&C Act may result in FDA taking regulatory action, including, but not limited to, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction.

WARNING LETTER RESPONSES

How to Respond:

- Send your response within 15 days of warning letter receipt, by email and in writing.
- Send emails to CTPCompliance@fda.hhs.gov or any other email addresses listed in the warning letter.
- Send written responses to the following address:

  DPAL-WL Response, Office of Compliance and Enforcement
  FDA Center for Tobacco Products, c/o Document Control Center
  Building 71, Room G335
  10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002
- Include in your response any unique identifier stated in the Warning Letter for tracking.
- If you have questions, contact the phone number identified in the Warning Letter.