

OVERVIEW OF WARNING LETTERS FOR ONLINE RETAILERS

Presented by the Office of Compliance and Enforcement

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The FDA logo is a blue square with the letters "FDA" in white, bold, sans-serif font.

AGENDA

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





OVERVIEW OF INTERNET AND PUBLICATION SURVEILLANCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act):

- Gives the FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and any other tobacco products that the agency, through regulation, deems to be subject to its tobacco product authorities.
- The Final Deeming rule, published on May 10, 2016, deems 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 products, subject to FDA's tobacco product authorities in Chapter IX of the FD&C Act and regulations.
- The rule became effective on August 8, 2016.

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, batteries for electronic nicotine delivery systems (ENDS), and cigar tips.

FDA REGULATED TOBACCO PRODUCTS



Examples of Tobacco Products Regulated Before Deeming Rule	Examples of Regulated Tobacco Products Under the Deeming Rule
<ul style="list-style-type: none">• Cigarettes• Cigarette tobacco• Roll-Your-Own tobacco• Smokeless tobacco <p><i>This includes the components, parts, and accessories of these products.</i></p>	<ul style="list-style-type: none">• ENDS*• Pipe tobacco• Cigars• Hookah/Waterpipe tobacco• E-liquid• Dissolvable tobacco products not already regulated by FDA• Future tobacco products <p><i>This includes the components and parts of these products, but not their accessories.</i></p>

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

- 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 regulated tobacco industry for violations of the Federal Food, Drug & Cosmetic Act (FD&C Act) and its implementing regulations.

- CTP issues Warning Letters to regulated tobacco industry for violations under the FD&C Act and its implementing regulations
- For example, Warning Letters have been issued to online retailers for the following violations:
 - Selling tobacco products to individuals under the federal minimum age to purchase tobacco products.
 - 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 AND COMPLIANCE ACTIONS

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. 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.

- 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), in 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 action, including, but not limited to, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction.

Warning Letters are also posted on the FDA website

- Internet and Publication Surveillance:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

- State Retailer Compliance Check Inspections:

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



EXAMPLES OF VIOLATIONS

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- Selling tobacco products to individuals under the federal minimum age to purchase tobacco products.
- 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.

- 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 (21 C.F.R. § 1140.3).
- Effective December 20, 2019, an amendment to the FD&C Act raises 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 in violation of section 906(d)(5) of the FD&C Act.
- 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.

- The United States District Court for the District of Columbia recently issued an order vacating the health warning requirements for cigars and pipe tobacco set forth in 21 CFR §§ 1143.3 and 1143.5 and remanding 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

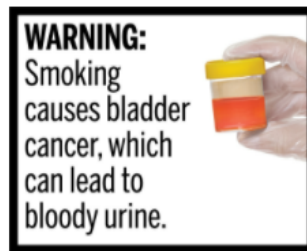
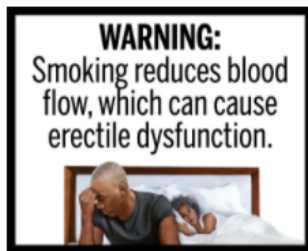
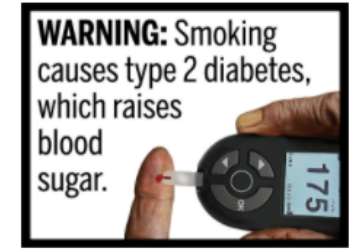
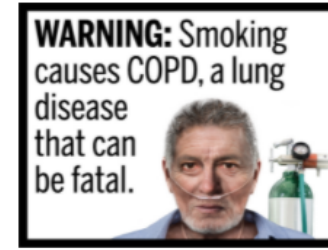


- Smokeless tobacco packages and advertisements must bear one of the four following warning label statements in accordance with an FDA-approved plan:
 - **WARNING:** This product can cause mouth cancer.
 - **WARNING:** This product can cause gum disease and tooth loss.
 - **WARNING:** This product is 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 August 18, 2021, a federal district court issued an order in the case of *R.J. Reynolds Tobacco Co. et al. v. FDA*, to postpone the effective date of the final rule. **The new effective date of the final rule is October 11, 2022. FDA encourages firms to submit cigarettes plans as soon as possible, and in any event by December 12, 2021.**



TOBACCO PRODUCTS WITHOUT REQUIRED MARKETING AUTHORIZATION



- All deemed new tobacco products, including ENDS products, must receive premarket authorization from FDA to be legally marketed.
- FDA is prioritizing enforcement of the premarket review requirements for certain ENDS products, including against retailers selling such products. Specifically, FDA is prioritizing enforcement against:
 - Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
 - All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent underage persons' access; and
 - Any ENDS product that is targeted to youth or whose marketing is likely to promote use of ENDS by youth.
- Per court order, premarket applications for many new tobacco products on the market as of August 8, 2016, including ENDS, were due to FDA by September 9, 2020. New tobacco products marketed without required marketing authorization risk FDA enforcement (except for “premium cigars”). See link below for FDA's enforcement priorities:
- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>

WARNING LETTERS

FDA has issued warning letters to companies for marketing unauthorized ENDS products that imitate packaging for food products such as Twinkies, feature cartoon characters such as SpongeBob SquarePants, and resemble children's toys such as a video game system or smartwatches.



E-Liquid



Food Products



ENDS Product



Video Game



ENDS Product



Smartwatch



E-Liquid



Cartoon

FDA has issued over 100 warning letters to companies who manufacture and operate websites selling ENDS products, specifically e-liquids, that lack premarket authorization, advising them that selling these products is illegal, and therefore they cannot be sold or distributed in the U.S. The firms did not submit a premarket tobacco product application (PMTA) by the Sept. 9, 2020, deadline.

FDA NEWS RELEASE

FDA Warns Firms to Remove Unauthorized E-liquid Products from Market in First Letters Issued to Manufacturers that Did Not Submit Premarket Applications by Deadline

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Section 911(a) 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.
- 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).

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.”



RESPONDING TO WARNING LETTERS

- 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.

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.

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 or 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.

