Product Compliance

FDLI Intro to Tobacco Regulation

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FDLI

Overview

- Labeling and Warning Requirements
- Product Registration and Ingredient Submission
- User Fees and Tobacco Taxation
- Marketing and Advertising Limitations and Requirements
- Retailer Requirements
- Product Standards

Labeling and Warning Requirements

Deemed **misbranded** under Section 903 if:

- The labeling is false or misleading;
- The package label does not contain
  - Name/place of business of manufacturer, packer, or distributor
  - Accurate statement of weight, measure, or count
  - Accurate statement of % domestic- and foreign-grown tobaccos
  - Statement that “Sale only allowed in the United States”
- Any word, statement, or other info required under the Act is not prominently placed;
- Does not bear adequate directions for use or warnings against use by children

  (if required by regulation)

Cigarette Labeling and Warning Requirements

- TCA requires cigarettes to bear one of the following labels (15 U.S.C. § 1333):
  - WARNING: Cigarettes are addictive.
  - WARNING: Tobacco smoke can harm your children.
  - WARNING: Tobacco smoke can cause fatal lung disease.
  - WARNING: Cigarettes cause cancer.
  - WARNING: Cigarettes cause strokes and heart disease.
  - WARNING: Smoking during pregnancy can harm your baby.
  - WARNING: Smoking can kill you.
  - WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
  - WARNING: Quitting smoking now greatly reduces serious risks to your health.

- Warning must comprise top 50% of front and rear panels of package
- Specific font and formatting requirements
- Random display and rotation requirements

Smokeless Tobacco Labeling and Warning Requirements

- TCA requires smokeless tobacco products to bear one of the following labels (15 U.S.C. § 4402):
  - 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.

- Warning must comprise 30% of the 2 principal display panels of package
- Specific font and formatting requirements
- Random display and rotation requirements

“Covered” Tobacco Products Labeling and Warning Requirements

- Deeming rule (compliance date of 8/10/2018) requires covered tobacco products to bear a nicotine addiction warning (21 C.F.R. 1143.3(a)(1)):
  - WARNING: This product contains nicotine. Nicotine is an addictive chemical.

- Includes nicotine e-liquids, hookah/waterpipe tobacco, RYO cigarette tobacco
- Warning must comprise 30% of the 2 principal display panels of package and be conspicuous and prominent
- Specific font and formatting requirements
- Warning can be on carton, outer container, wrapper, or permanent tag if package is too small to display required statement

Cigar and Pipe Tobacco Labeling and Warning Requirements

- District Court vacated the health warning requirements for cigars and pipe tobacco set forth in 21 CFR §§ 1143.3 and 1143.5 and remanding the warning requirements back to the Agency
- *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, No. 1:16-cv-01460 (D.D.C. September 11, 2020)
- Cigar and pipe tobacco firms may choose to voluntarily comply with these health warning provisions.
- FDA will continue to enforce the other requirements it was already enforcing for cigars and pipe tobacco under the TCA.

Graphic Health Warnings for Cigarettes

- TCA requires FDA to develop graphic warning labels for cigarette packages and advertisements.
- On June 22, 2011, FDA published a final rule requiring color graphics depicting the negative health consequences of smoking to accompany the textual warning statements included in the TCA.
- Nine proposed rotating graphic images on packaging
- 1-800-QUIT-NOW on label

Graphic Health Warnings for Cigarettes

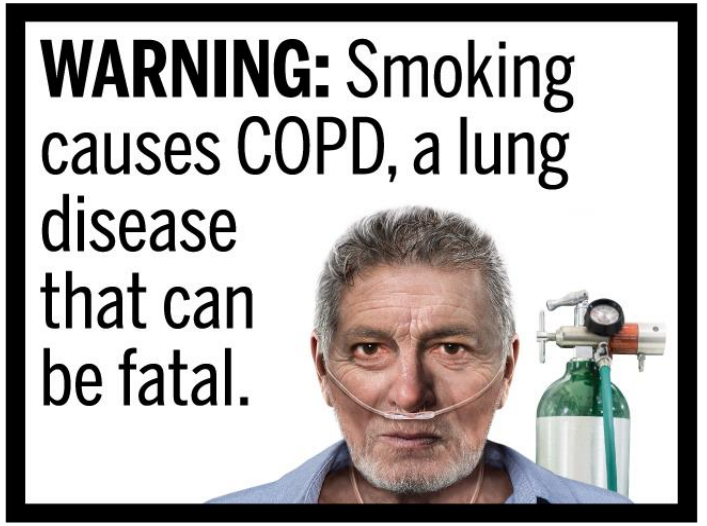
- FDA was sued over the 2011 graphic health warning final rule
- *R.J. Reynolds Tobacco Co., et al., v. Food & Drug Administration, et al.*, 696 F.3d 1205 (D.C. Cir. 2012)
- Court vacated the rule on First Amendment grounds and remanded the matter to the agency
- FDA began undertaking research related to graphic health warnings

Graphic Health Warnings for Cigarettes

- In 2018, public health groups filed a lawsuit challenging FDA on the delay in issuing the new graphic warning rule.
- In March 2019, court ordered FDA to publish a proposed rule by August 2019 and a final rule by March 2020.
- On March 18, 2020, FDA issued a final rule requiring new graphic warnings **"Required Warnings for Cigarette Packages and Advertisements"**
- Aug. 10, 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, to postpone the effective date of the final rule.
- The new effective date of the final rule is Oct. 6, 2023, but FDA encourages submission of plans no later than Dec. 7, 2022.

Graphic Health Warnings for Cigarettes

- 11 new graphic warnings in final rule.
- Textual warning statements accompanied by color graphics.
- Photorealistic images, depicting the negative health consequences of cigarette smoking.
- Depict some of the lesser-known, serious health risks of smoking.
- Must be randomly and equally displayed and distributed.
- Must appear prominently
- Top 50% of the front and rear panels
- 20% of the area at the top of advertisements



Product Registration and Ingredient Submission

U.S. Establishment Registration

- All establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product marketed in the United States must re-register with FDA by December 31 of each year
- Accomplished via TRLM NG module or paper submission.
- Currently, only domestic establishments are required to register, but the TCA contemplates that foreign establishments will also be required to register in the future
- To reduce redundant submissions, FDA encourages the owner of each domestic establishment to act as the agent of all operators within the business structure in submitting registration information
- FDA guidance (rev. Dec. 2017): https://www.fda.gov/media/78165/download
- Permitting from Alcohol and Tobacco Tax and Trade Bureau also needed

Product Listing

- At the time of registration, all registrants must also submit to FDA a detailed list of all tobacco products manufactured, prepared, compounded, or processed by the establishment and marketed in the U.S.
- Applies only to finished tobacco products at this time.
- Must include copies of product labels with product list; representative advertisements and “consumer information”.

Product Listing

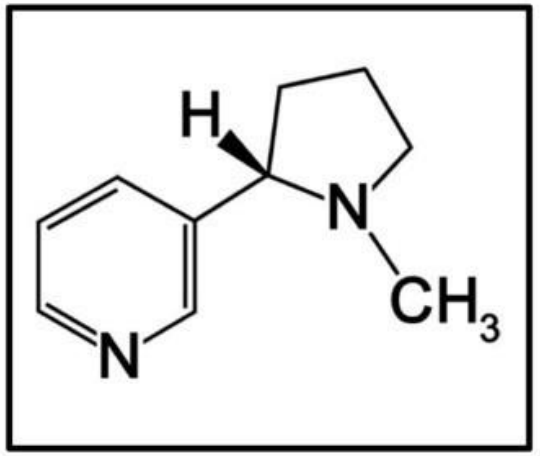
- FDA's guidance clarifies that e-liquid manufacturers do not need to submit labels for all product variations.
- FDA recognized that variations in package size, nicotine strength, Propylene Glycol (PG)/Vegetable Glycerin (VG) ratio, and flavor could result in thousands of individual product labeling submissions.
- Registrants may submit a separate "package label plan", which is a model/generic product label with placeholder text for the specific variations, along with a "product variation index" which lists all the variations for a specific product, e.g., package size, nicotine strength, PG/VG ratio and flavor

Product Listing

- Registrants must also file a biannual (June 30 and Dec. 31) report of certain changes to their product lists:
  - any products introduced for commercial distribution that have not been included on a previous list;
  - any products that you have discontinued manufacturing, preparing, compounding, or processing;
  - any products that you have resumed manufacturing, preparing, compounding, or processing after previously reporting them as discontinued; and
  - any material change to information previously submitted

Ingredient Listing

- Manufacturers and importers of cigarettes, cigarette tobacco, RYO, smokeless tobacco, and deemed products are required to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of the tobacco product by brand and by quantity
- Included Information
  - Manufacturer/importer identification
  - Product identification
  - Ingredient identification
    - Single Chemical Substances
    - Leaf Tobacco
    - Complex Purchased Ingredients
    - Reaction Products
  - Part to which ingredient is added
  - Ingredient quantity



Ingredient Listing

- Ingredient listing information required to be submitted to FDA
  - By December 22, 2009 for products on the market as of June 22, 2009.
  - At least 90 days prior to delivery for introduction for products not on the market as of June 22, 2009.
- Finished tobacco products regulated by the final deeming rule, such as cigars, dissolvables, hookah tobacco, nicotine gels, pipe tobacco, and electronic nicotine delivery systems (including e-liquids), entering the market as of August 8, 2016:
  - November 8, 2018 for "small scale tobacco product manufacturers" (All other ingredient listing submissions for "finished tobacco products" regulated by the final deeming rule had a compliance date of May 8, 2018.)
  - For deemed finished tobacco products entering the market **after** August 8, 2016, at least 90 days before the product is delivered for introduction into interstate commerce.

Ingredient Listing

- Applies to finished tobacco products only.
- Components and parts sold separately from other tobacco products are finished tobacco products only if sold in final packaging intended for consumer use.
- Components and parts either sold separately as finished products or as components or parts of other finished products only require ingredient listing if:
  - Made or derived from tobacco;
  - Containing ingredients that are burned, aerosolized or ingested during tobacco product use (e.g., cigarette paper).

Ingredient Listing

- FDA's guidance clarifies that ingredient listing can be satisfied by providing one listing that corresponds to multiple products, provided:
  - Identical per weight composition of ingredients with respect to their components and parts;
  - All different brands/subbrands and products sizes are identified.

User Fees and Tobacco Taxation

User Fees

- The Act requires FDA to assess and collect user fees from each manufacturer and importer of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco. See 21 CFR Part 1150.
- Information must be submitted to FDA so the Agency can calculate the user fees.
- Fees are collected on a quarterly basis, and each quarterly assessment is allocated among classes of tobacco products.
  - The class allocation is based on each tobacco product class's volume of tobacco products removed into commerce.
  - Within each tobacco product class, an individual domestic manufacturer or importer is assessed a user fee based on its market share for that tobacco product class.
- Products may be deemed misbranded if user fees are not paid.

User Fees

2021 Tobacco User Fee Assessment Formulation by Product Class

FY 2021	Revenue Target
Full Year	$712,000,000
Per Quarter	$178,000,000

Tobacco Product Class	FY 2021 Class Est, Taxes From TTB Based on 2019 TTB data [1]	Allocation by Class (Percent) Based on 2019 TTB data [1]	Amount Per Quarter (Final Quarter Amount
Cigarettes	$4,356,931,474	85.2309%	$151,711,002
Roll-Your-Own Tobacco	$2,195,100	0.0429%	$76,362
Snuff	$66,896,502	1.3086%	$2,329,308
Chewing Tobacco	$3,110,506	0.0608%	$108,224
Cigars	$641,872,545	12.5564%	$22,350,392
Pipe Tobacco	$40,907,719	0.8002%	$1,424,356
Total	$5,111,913,847	99.9998%	$177,999,644
			Total 2021 Amount $711,998,576

User Fees

- Alcohol and Tobacco Tax and Trade Bureau (TTB) – TTB Industry Circular 2020-2 postponed tax payments for tobacco products
- FDA has clarified it cannot extend the deadlines for monthly reporting of tobacco user fee information
- FDA cannot suspend or delay the deadline for tobacco product user fees

Taxation of Tobacco

- Anyone who manufacturers, imports, or engages in export operations of tobacco products (cigarettes, cigars, chewing tobacco, snuff, pipe tobacco, RYO) must obtain a permit from TTB
- Federal excise tax on cigarettes, snuff, chewing, pipe, and RYO tobacco, cigars

Taxation of Tobacco

- All fifty states and hundreds of localities have excise taxes on cigarettes
- Most states impose taxes on tobacco products aside from cigarettes
- Many states have excise taxes on e-cigarettes

E-Cigarette Tax

- Proposed taxes on tobacco products in pending infrastructure bill
- Would fall most heavily on consumers
- Increase cigarette tax and other products to achieve parity with cigarettes

	TAX INCREASE	FEDERAL TAX AFTER FEDERAL TAX INCREASE
CIGARETTES	100%	$2.01 PER PACK
LARGE CIGARS (15 GRAMS)	NOT COMPARABLE	$1.64 PER CIGAR
DIPPING TOBACCO (1.2 OZ)	1,677%	$2.01 PER CAN
ROLL-YOUR-OWN (0.65 OZ)	100%	$2.01 PER POUCH
SNUS (24 POUCH CAN)	2,892%	$2.40 PER CAN
VAPOR PRODUCTS (5MG POD)	NOT TAXED PREVIOUSLY	$2.22 PER POD
NICOTINE POUCHES (8MG)	NOT TAXED PREVIOUSLY	$8.90 PER CAN

Note: Above only illustrates the new federal tax rates. These products are also taxed at state and local levels.
Source: Build Back Better Act.

https://taxfoundation.org/house-tobacco-proposal-bidens-tax-pledge/

THE PACT ACT

The Prevent All Cigarette Trafficking ("PACT") Act

- Originally passed in 2009 to amend the Jenkins Act of 1949
  - Prohibits use of USPS to deliver cigarettes and smokeless tobacco products to consumers
  - BUT business-to-business deliveries exempted with application
  - Requires sellers to register with ATF and tobacco tax administrators of states where shipments are made or advertisements are disseminated, and file monthly sales reports

2020 Amendment

- On December 27, 2020 – Congress amended the PACT act to apply to all vaping products and e-cigarettes
  - Effective on March 28, 2021
- FedEx (effective March 1, 2021) and UPS (effective April 5, 2021) have prohibited transport of vapor products
- October 22, 2021 – USPS published a final rule regarding the mailing of ENDS
  - Essentially applies to any substance vaped, including synthetic nicotine, CBD, THC, etc.
  - Maintains a business purposes exception permitting the shipment of ENDS between legally operating businesses engaged in tobacco product manufacturing, distribution, wholesale, etc.

Marketing and Advertising Limitations and Requirements

Advertising of Tobacco Products

- Manufacturers, retailers, and distributors of cigarettes and smokeless tobacco are prohibited from:
  - Sponsoring athletic, musical, artistic, or other social or cultural event;
  - Marketing, licensing, distributing, selling any item or service with a brand name, logo, etc.;
- No free samples of tobacco products (exception for smokeless products distributed in a qualified adult-only facility in limited quantities)

Warning Statements on Advertisements

- For cigarette tobacco, roll-your-own tobacco, and covered tobacco products, it is unlawful for the manufacturer, packager, importer, distributor, or retailer of the tobacco product to advertise without the required warning statement.
- Warning must:
  - Appear on upper portion of ad, within trim area;
  - Occupy at least 20% of the ad;
  - 12 point font minimum and occupying greatest amount of warning area;
  - Font and formatting requirements;
  - Rectangular border.

Retailer Requirements

Requirements for Retailers

- Check photo ID of everyone under age 27 who attempts to purchase cigarettes, cigarette tobacco, or RYO tobacco
- No sales to minors
- No free samples to consumers
- No vending machine sales, unless adult-only facility
- No “loosies”
- No cigarettes, cigarette tobacco, RYO tobacco with characterizing flavors
- No breaking open packages to sell in smaller amounts.

Warning Statement Requirements for Retailers

- Beginning August 10, 2018:
  - No cigarette or RYO tobacco products without a warning statement on package
  - No advertisements for cigarette or RYO products without a warning statement
- The warning statement requirements for advertisements apply directly to a retailer only if the retailer is responsible for or directs the health warning.
- Does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that:
  - Does not contain a health warning; or
  - Contains a health warning that has been materially altered by the retailer.

Retailer Safe Harbor

- *Retailers* may take advantage of a "safe harbor" that allows them to sell pre-August 10, 2018 products without the nicotine addiction warning (or with a deficient warning) *indefinitely* (i.e., until inventory of such products runs out), provided that the non-compliant product has packaging/labeling that:
  - Contains a health warning [i.e., a Prop 65 or other health warning];Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor, who has the required permitting
  - Is not materially altered by the retailer
- See 21 CFR 1143.3(a)(3).

Retailer Requirements

- Tobacco 21
  - December 20, 2019.
  - Raised minimum age for sale of tobacco products to 21.
  - Retailer training is not a requirement under Tobacco 21.
- Compliance check inspections
  - Undercover buy inspections
- Tobacco retail compliance webinars
- Searchable retailer inspection database

Requirements for Retailers

- Beginning February 2020, FDA will prioritize enforcement – including against retailers – of premarket review requirements for flavored (other than tobacco or menthol flavored), cartridge-based ENDS products that have not received premarket authorization to anyone, regardless of age

Product Standards

Tobacco Product Standards

- Section 907 of the TCA established two tobacco product standards and referred two other questions to TPSAC
- Allows FDA to adopt other tobacco product standards that are appropriate for the protection of the public health based on:
  - Risks and benefits to the population as a whole;
  - Increased or decreased likelihood that existing tobacco users will stop using the products;
  - Increased or decreased likelihood that those who do not use tobacco products will start using the products.
- Technical achievability will be considered

Tobacco Product Standards

- Ban on Characterizing Flavors in Cigarettes
  - As of September 22, 2009, cigarettes may not contain any artificial or natural flavor, or any herb or spice (except for tobacco or menthol).
- Pesticide Chemical Residue
  - As of June 2011, manufacturers may not use foreign grown tobacco that contains a pesticide chemical residue that exceeds applicable U.S. tolerances.
  - There are currently no such established tolerances in effect

Tobacco Product Standards

- New standards must be promulgated through APA notice and comment rulemaking
  - Publication of a notice of proposed rulemaking in the federal register
  - 60 days for public comment
  - FDA must address comments in issuance of final rule
- FDA will develop standards based on consultation with other federal agencies and international standard-setting organizations, and through workshops with industry and consumer organizations
- New standards become effective one year after finalization unless FDA deems it necessary for effective date to be earlier, if appropriate for protection of the public health

Proposed Tobacco Product Standards

- On January 2017 – FDA issued a proposed rule entitled, “Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products”
- March 2018 – ANPRM to obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes
- CTP Director Brian King recently announced FDA’s continued intent to finalize product standards for:
  - Reduced nicotine content in cigarettes
  - Menthol ban for cigarettes
  - Flavor ban in all cigars and cigarillos

Thank You!

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