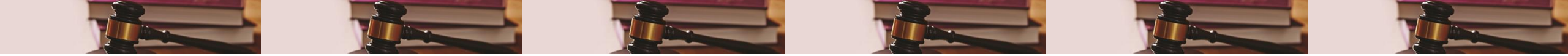

Compliance Central with FDA Center Compliance Directors: Part II

Eric Nelson, Director, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, FDA

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Moderated by **Suzan Onel**, Partner, Kleinfeld, Kaplan & Becker, LLP

FDLI

FDLI'S ENFORCEMENT, LITIGATION, AND COMPLIANCE CONFERENCE

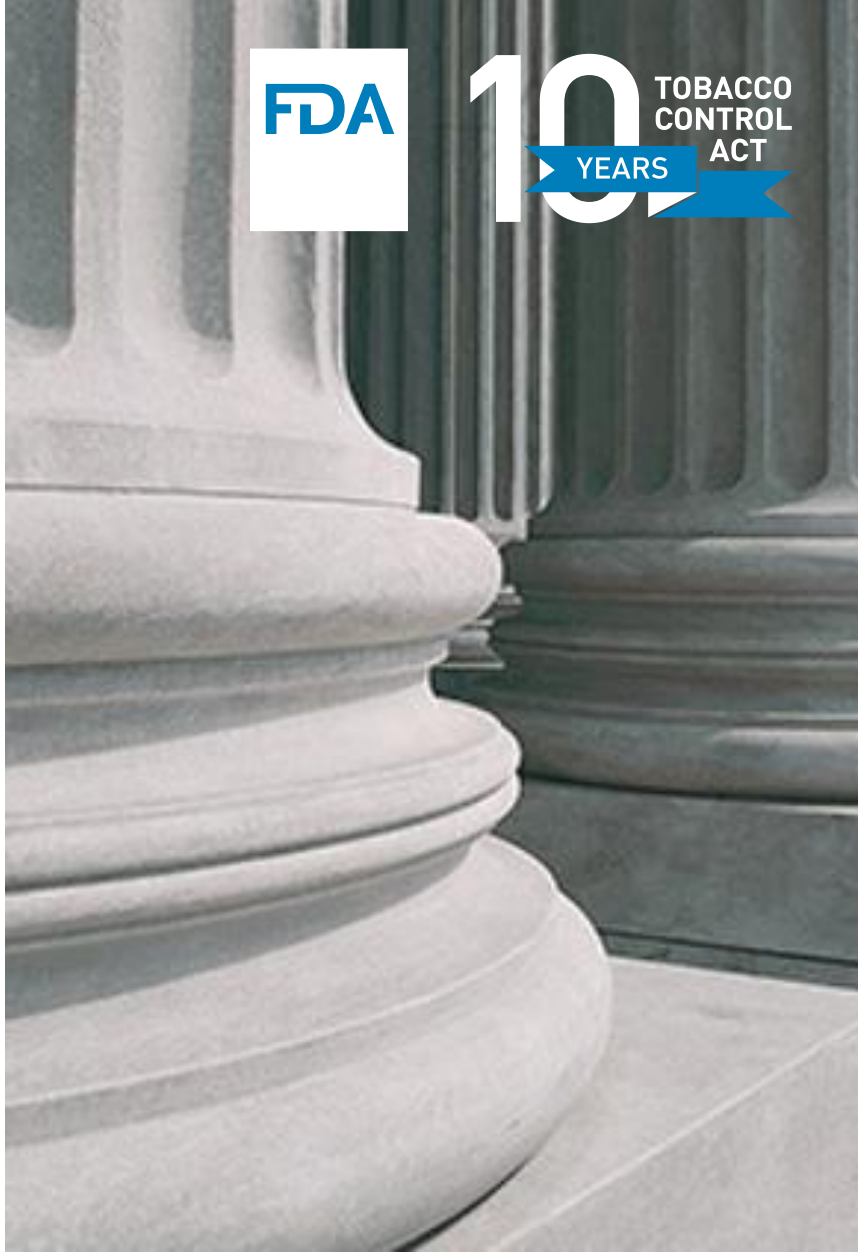
CENTER FOR TOBACCO PRODUCTS

OFFICE OF COMPLIANCE AND ENFORCEMENT

2019 UPDATE

Ann Simoneau, Director
Office of Compliance and Enforcement
Center for Tobacco Products

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



2019 GUIDANCE DOCUMENTS

Name	Type	Date Issued
Use of Investigational Tobacco Products (Revised)	Draft Guidance	02/20/2019
Enforcement Policy for Certain Marketed Tobacco Products	Draft Guidance	02/28/2019
FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)	Guidance	03/08/2019
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)	Guidance	03/08/2019
Modifications to Compliance Policy for Certain Deemed Tobacco Products	Draft Guidance	03/13/2019
Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops	Guidance	03/22/2019
Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)	Guidance	06/11/2019

2019 PROPOSED RULES

Name	Type	Date Issued
Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports	Proposed Rule	04/02/2019
Premarket Tobacco Applications and Recordkeeping Requirements	Proposed Rule	09/25/2019
Tobacco Products; Required Warnings for Cigarette Packages and Advertisements	Proposed Rule	8/16/2019

COMPLIANCE TRAINING AND EDUCATION WEBINARS

- More than 70 compliance training webinars on federal tobacco regulations on FDA's website.
- Designed to provide compliance education and information to small businesses and to help tobacco retailers, importers, and manufacturers better understand the agency's regulatory requirements.

Examples of Webinars

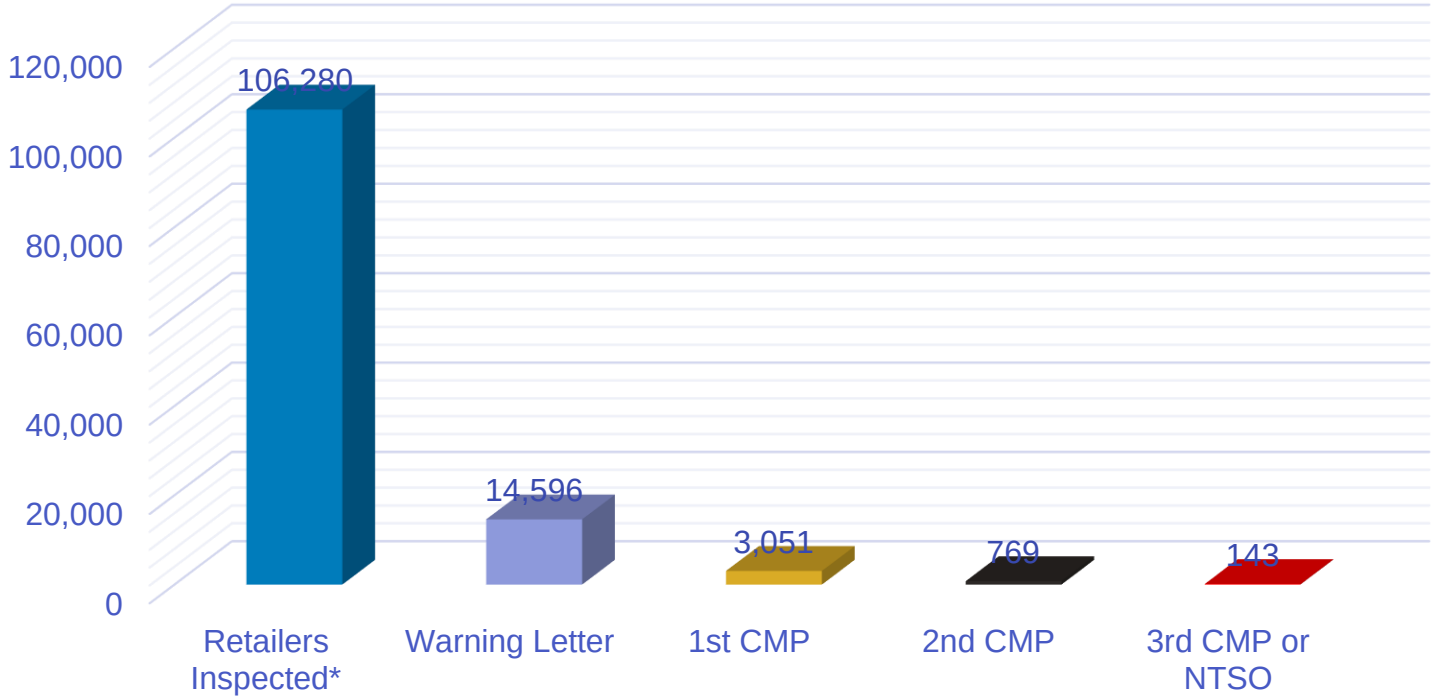
Introduction to Tobacco Product Recalls

Retailer Requirements: New Warning Statement Requirements for Certain Tobacco Products

FY 2019 Tobacco Retailer Inspection Results:

- Over 146,000 tobacco retailer inspections completed.
- Over 14,000 Warning Letters issued.
- Over 4,700 Civil Money Penalty Complaints issued.
- 13 No-Tobacco-Sale Order Complaints issued.

RETAILER COMPLIANCE CHECK INSPECTION PROGRAM



Cohort of Retailers Inspected After the Final Deeming Rule Became Effective (August 8, 2016)

*Enforcement data from routine undercover buy tobacco retailer inspections conducted from August 8, 2016 through September 30, 2017.

2019 LETTERS TO LARGE RETAIL CHAINS

Letters to Multiple Large Retail Chains with High Violation Rates

- In March and April 2019, FDA sent letters to 13 large national retail chains that had violation rates of 15 percent or more (since the inception of the tobacco retailer inspection program in 2010).
- In these letters, FDA outlined its concerns with retailer chains' violative history and asked these retailers to submit their plans describing how they would address and mitigate illegal sales to minors in their retail establishments.

Large Retail Chains with High Violation Rates	
Walmart Inc.	7-Eleven, Inc.
ExxonMobil Corporation	The Kroger Co.
Walgreens	BP PLC
Citgo Petroleum Corporation	Chevron Corporation
Sunoco LP	Shell
Family Dollar Stores, Inc.	Marathon Petroleum Corporation
Casey's General Stores, Inc.	

SURVEILLANCE AND MANUFACTURING INSPECTIONS

- FDA conducts surveillance of websites, social media, magazines, and other publications that market, advertise, and sell regulated tobacco products, and takes enforcement action when violations are found.
  - In FY 2019, FDA issued more than 100 Warning Letters.
- FDA conducts biennial inspections of registered tobacco product manufacturers to determine compliance with existing laws and regulations. Office of Regulatory Affairs' tobacco cadre investigators conduct these inspections.
  - In FY 2019, FDA conducted more than 275 tobacco manufacturing inspections.
- FDA conducts inspections of vape shop establishments that may be manufacturers, retailers, or both, to determine compliance.
  - In FY 2019, FDA conducted more than 1,000 inspections of vape shops.

2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: USER FEES

- FDA assesses and collects quarterly user fees from manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco.
- In FY 2019, FDA issued six Warning Letters to companies for failure to pay user fees.

Tobacco User Fee Assessment Formulation by Product Class

2020 Tobacco User Fee Assessment Formulation by Product Class

FY 2020	Revenue Target
Full Year	$712,000,000
Per Quarter	$178,000,000

Tobacco Product Class	FY 2020 Class Est. Taxes From TTB Based on 2018 TTB data [1]	Allocation by Class (Percent) Based on 2018 TTB data [1]	Amount Per Quarter (Final Quarter Amount)
Cigarettes	$4,588,727,872	86.0996%	$153,257,288
Roll-Your-Own Tobacco	$2,297,274	0.0431%	$76,718
Snuff	$67,933,537	1.2746%	$2,268,788
Chewing Tobacco	$3,523,061	0.0661%	$117,658
Cigars	$623,269,077	11.6945%	$20,816,210
Pipe Tobacco	$43,802,615	0.8218%	$1,462,804
Total	$5,329,553,435	99.9997%	$177,999,466
			Total 2020 Amount $711,997,864

1 Source: Alcohol and Tobacco Tax and Trade Bureau, National Revenue Center, Report Symbol TTB S 5210-12-2018 (March 12, 2019). https://www.ttb.gov/tobacco/tobacco-stats.shtml

2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: UNAUTHORIZED TOBACCO PRODUCTS

- FDA sent letters to more than 80 companies seeking information about the marketing status of more than 110 tobacco products.
- FDA issued eight Warning Letters to companies for manufacturing, selling and/or distributing over 200 tobacco products without the required FDA premarket authorization.
  - In April 2019, FDA issued a Warning Letter to Smokin Joes that included 34 cigarette products.
  - In April 2019, FDA issued a Warning Letter to Dynamic Creations that included 18 e-liquid products.
  - In October 2019, FDA issued a Warning Letter to EonSmoke, LLC, that included nearly 100 flavored e-liquid products.

2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: MODIFIED RISK TOBACCO PRODUCTS (MRTP)

- In September 2019, FDA issued a Warning Letter to JUUL Labs Inc. for marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers. The Warning Letter stated that FDA has determined that JUUL marketed its products as modified risk tobacco products (MRTP) without an appropriate FDA order in effect. FDA also sent a letter to the company expressing concern and requesting documents and information about several issues regarding JUUL's outreach and marketing practices.
- In October 2019, FDA issued a Warning Letter to EonSmoke, LLC, for engaging in labeling, advertising, and/or other activities directed to consumers that explicitly and/or implicitly presented ENDS products sold or distributed by the company as having a lower risk of tobacco-related disease or as less harmful than other commercially marketed tobacco products.

2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: KID APPEALING TOBACCO PRODUCTS

- FDA issued dozens of Warning Letters to e-liquid manufacturers whose products used misleading imagery that imitated kid-friendly food products.

E-liquid

Food product

E-liquid

Food Product

E-liquid

Food Product

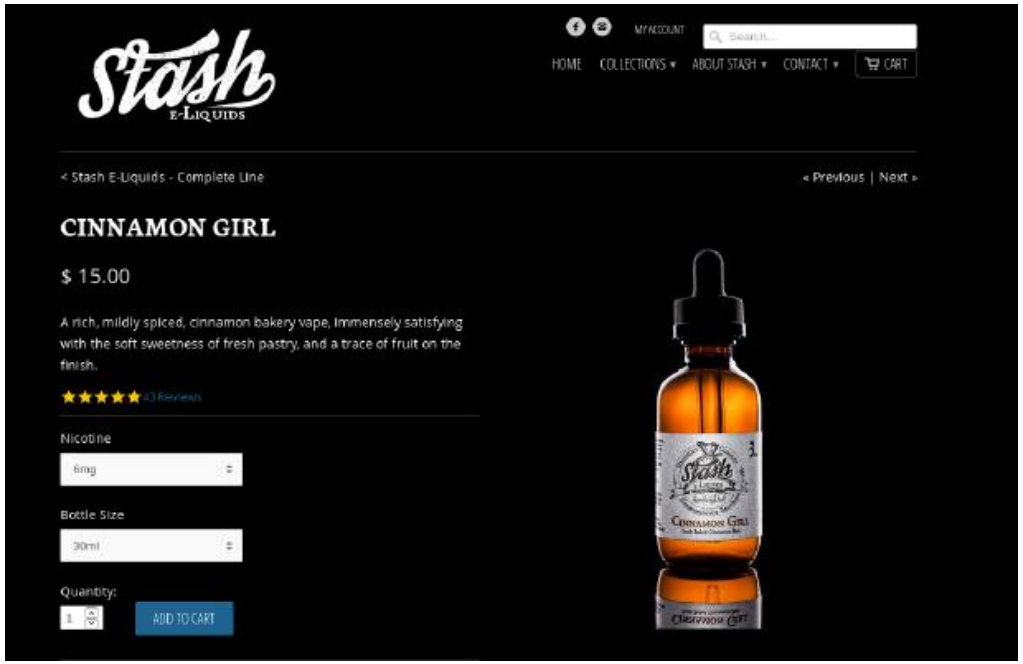
2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: DRUG IMITATING TOBACCO PRODUCTS

- In April 2019, FDA issued Warning Letters to a manufacturer, Undisputed Worldwide, and a retailer, EZ Fumes, for selling 2 e-liquid products with labeling and/or advertising that caused them to resemble prescription cough syrup Actavis Prometh with Codeine and Hi-Tech Promethazine Hydrochloride and Codeine.

2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: WARNING STATEMENTS

- In 2019, FDA has issued over 60 Warning Letters for failure to display or properly display the nicotine warning statement on the packages or in the advertisements of tobacco products, such as e-liquids, ENDS, and waterpipe tobacco.

Before



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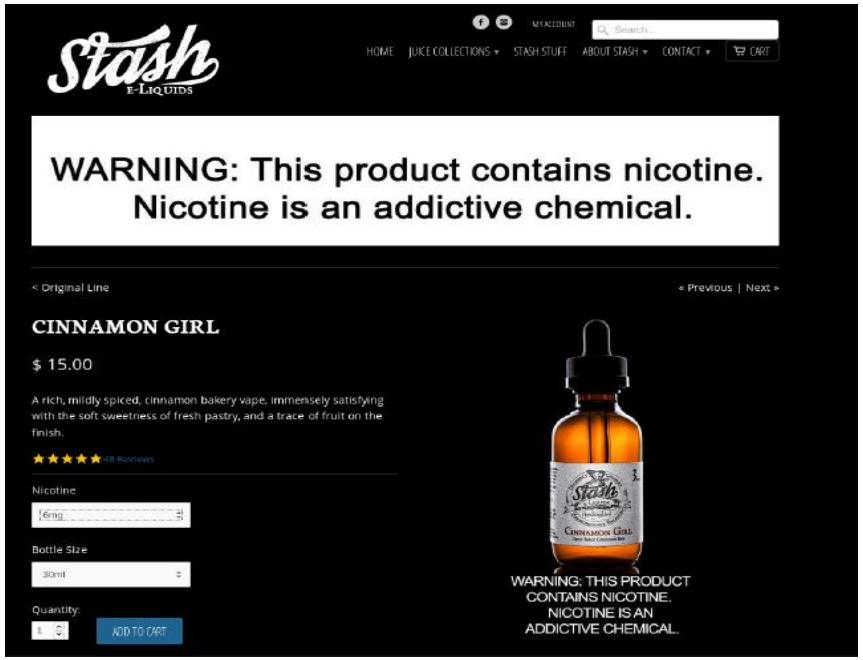
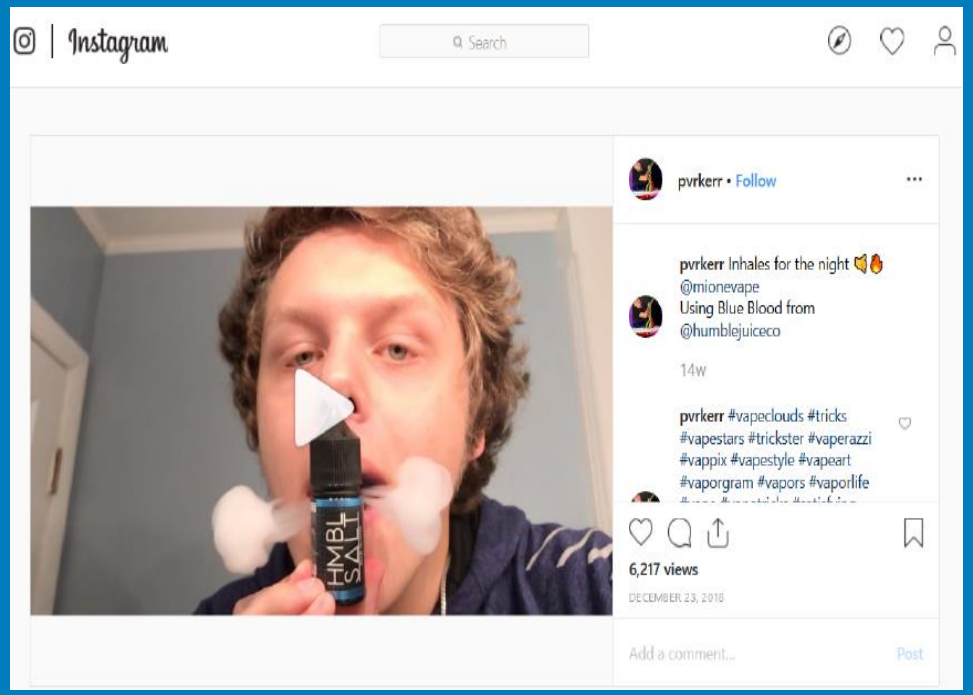


2019 COMPLIANCE AND ENFORCEMENT ACTIVITIES: SOCIAL MEDIA INFLUENCERS

- In June 2019, FDA and FTC issued joint Warning Letters to four manufacturers of flavored e-liquids whose social media influencer posts failed to include the required nicotine warning statement.



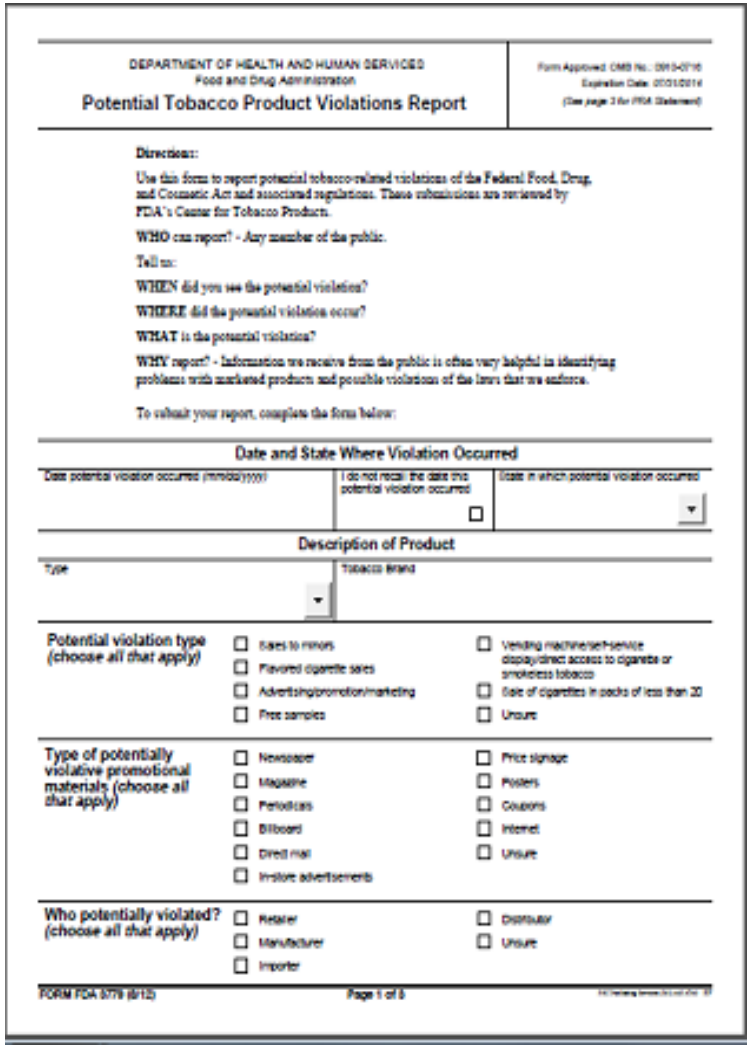
OTHER COMPLIANCE ACTIVITIES: SAFETY REPORTING PORTAL

- FDA reviews reports of tobacco product problems or adverse events that the agency receives through the Department of Health and Human Services' (HHS) Safety Reporting Portal (SRP) and from other sources, to better understand the events and to inform actions to protect the public health.
- FDA encourages industry, public health professionals, other stakeholders, and the public to utilize the SRP to help the Agency gather information on problems and adverse events associated with tobacco products.

OTHER COMPLIANCE ACTIVITIES: POTENTIAL TOBACCO PRODUCT VIOLATION REPORTS

Potential Tobacco Product Violation Reports (PTVR)

- Stakeholders and other members of the public are encouraged to report potential tobacco product violations to the FDA through the PTVR web portal.
- FDA reviews all reports of potential tobacco violations submitted and may initiate an investigation of the complaint.
- FDA investigations of some of these reports have resulted in Warning Letters and other actions.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Potential Tobacco Product Violations Report

Form Approved: OMB No. 0910-0716
Expiration Date: 07/31/2014
(See page 2 for PRA Statement)

Directions:

Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

WHO can report? - Any member of the public.

Tell us:

WHEN did you see the potential violation?

WHERE did the potential violation occur?

WHAT is the potential violation?

WHY report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

Date and State Where Violation Occurred

Date potential violation occurred (mm/dd/yyyy) | ☐ I do not recall the date the potential violation occurred | State in which potential violation occurred

Description of Product

Type | Tobacco Brand

Potential violation type *(choose all that apply)*

☐ Sales to minors
☐ Flavored cigarette sales
☐ Advertising/promotion/marketing
☐ Free samples
☐ Vending machine/self-service display/direct access to cigarette or smokeless tobacco
☐ Sale of cigarettes in packs of less than 20
☐ Unsure

Type of potentially violative promotional materials *(choose all that apply)*

☐ Newspaper
☐ Magazine
☐ Periodicals
☐ Billboard
☐ Direct mail
☐ Instore advertisements
☐ Price signage
☐ Posters
☐ Coupons
☐ Internet
☐ Unsure

Who potentially violated? *(choose all that apply)*

☐ Retailer
☐ Manufacturer
☐ Importer
☐ Distributor
☐ Unsure

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2019 NATIONAL YOUTH TOBACCO SURVEY RESULTS

- In November 2019, FDA and CDC published 2019 NYTS data in the Journal of the American Medical Association (JAMA).
- The data showed that current e-cigarette use among youth has continued at its alarming increase, with 27.5% of high school students and 10.5% of middle school students reporting current use of e-cigarettes.
- The data also showed that more than five million U.S. middle and high school students were current e-cigarette users.
- Of exclusive e-cigarette users, 2.4 million used flavored e-cigarettes.
- The results showed that 34.2 percent of current high school e-cigarette users in 2019 used the product frequently (use on 20 or more days in the last 30 days). In total, 1.6 million middle school and high school current e-cigarette users were frequent users, with nearly one million using e-cigarettes daily.

LITIGATION OVER 2017 COMPLIANCE POLICY

- As a result of litigation over the 2017 Compliance Policy, a court ordered that applications for marketing orders for deemed tobacco products on the market as of Aug. 8, 2016 must be filed within 10 months of the order (no later than May 12, 2020).
  - Products for which applications have not been filed within this period shall be subject to FDA enforcement action.
  - Products for which applications have been timely filed may remain on the market for up to a year (no later than May 12, 2021) while FDA reviews the application.
  - If FDA has not made a final decision within a year, those products must come off the market or be subject to enforcement.
- The order does not restrict FDA's authority to enforce premarket review requirements before the close of either the 10-month application submission period or the FDA application review period.

COMPLIANCE AND ENFORCEMENT REPORT

- In October 2019, FDA issued an updated Compliance and Enforcement Report for CTP's Office of Compliance and Enforcement (OCE).
- The report details the accomplishments and activities of OCE from October 2013 to December 2018.


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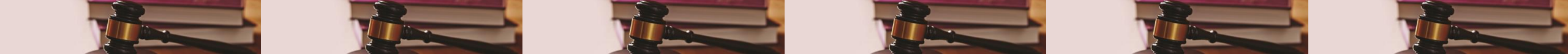

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