



Tobacco Enforcement Challenges and Recent Actions

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FDLI Enforcement, Litigation and Compliance Conference

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Beth G. Oliva, Esq.
Fox Rothschild LLP
December 13, 2018



FDA Enforcement Actions 2018

- In 2018, FDA has both:
 - increased enforcement efforts, and
 - begun to use expanded tools in enforcement efforts

FDA Enforcement Actions 2018

- **April 2018** – Announcement of “Youth Tobacco Prevention Plan”
 - “large-scale, undercover nationwide blitz” to crack down on underage sales of JUUL
 - Sent 40 warning letters
 - Contacted eBay over sales of JUUL
 - Sent document request letter to JUUL for information and documents relating to marketing

FDA Enforcement Actions 2018

- **May 2018**

- FDA partners with FTC to send warning letters to companies allegedly selling e-cigarette products marketed to children
- FDA sends document requests to four additional companies



Exhibit A



Exhibit B



Exhibit A



Exhibit B



FDA Enforcement Actions 2018

- **June 2018**

- Commissioner Gottlieb first announces increase in youth usage based on data from 2018 National Youth Tobacco Survey (NYTS)

- **August 2018**

- Announcement that the “The Real Cost” campaign has resulted in savings of “more than \$31 billion for youth, their families and society at large by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity and increased disability”

FDA Enforcement Actions 2018

- **September 2018**

- Commissioner Gottlieb announces additional “blitz” which is the “largest coordinated enforcement effort in the FDA’s history” resulting in 1300 warning letters and civil money penalties to retailers for underage sales
- FDA sends letters to JUUL, Altria (Mark Ten), RJ Reynolds (Vuse), JTI (Logic) and Fontem Ventures (blu) asking for plans on “how they will address the widespread youth access and use of their products”
- FDA launches new “The Real Cost” campaign for youth e-cigarette use

FDA Enforcement Actions 2018

- **October 2018**

- FDA meets with the five major manufacturers to discuss their plans
- FDA sends warning letters to e-cigarette companies selling e-liquids with unapproved drug claims, and that falsely claim to be FDA approved
- FDA issues 21 letters to companies seeking information whether 40 e-cigarette products were properly on the market as of August 8, 2016

FDA Enforcement Actions 2018

- **November 2018**

- November 15, 2018 announcement re changes to compliance policy
- Warning letter to Electronic Lotus, Inc.
 - Products not on market as of August 8, 2016
 - Products are misbranded because labeling is false and/or misleading and appeals to youth
 - Products are not listed on domestic manufacturer product listing

Cereal Treats Crunch



Cereal Treats Charms





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December 13, 2018





The national trade association executing a coordinated federal lobbying & state lobbying strategy combined with an integrated public affairs strategy to protect the vapor industry

Who We Are

- ✓ Device Manufacturers
- ✓ E-Liquid Manufacturers
- ✓ Wholesalers
- ✓ Distributors
- ✓ Retail Vape Shops
- ✓ Online Sellers
- ✓ Importers
- ✓ Suppliers





Board of Directors



Who We Are



November 15, 2018



- “Today, I’m pursuing actions aimed at addressing the disturbing trend of youth nicotine use and continuing to advance the historic declines we’ve achieved in recent years in the rates of combustible cigarette use among kids.”
- “I saw the opportunity to advance new technologies like electronic nicotine delivery systems (ENDS) as an alternative to cigarettes for adults who still seek access to satisfying levels of nicotine, without all the deadly effects of combustion.”
- “I believed then – and I continue to believe – that we must recognize the potential for innovative, less harmful products that can efficiently deliver satisfying levels of nicotine to adults who want them.”
- “[A]ny policy accommodation to advance the innovations that could present an alternative to smoking – particularly as it relates to e-cigarettes – cannot, and will not, come at the expense of addicting a generation of children to nicotine through these same delivery vehicles. This simply will not happen. I will take whatever steps I must to prevent this.”

November FDA Announcement on Flavored Tobacco Products

The logo for the U.S. Food & Drug Administration, featuring the letters "FDA" in a bold, blue, sans-serif font.

U.S. FOOD & DRUG
ADMINISTRATION

1. Proposed Regulation on Flavored Combustible Products
2. Proposed Limits on Retail Sales of Certain Vapor Flavors
3. Proposed Limits on Online Sales of Certain Vapor Flavors
4. Additional Youth Marketing Enforcement Actons

1.

FDA Challenges Flavored Combustible Tobacco

- FDA will propose to ban menthol in combusted tobacco products, including cigars and cigarettes, via rule.
- FDA proposed removing flavored cigars from the extended PMTA compliance date and to eventually ban all flavors in cigars.

“I believe these menthol-flavored products represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes.”

Commissioner Gottlieb

2.

Restrictions on Brick & Mortar Retail Sales of Flavored ENDS

- GOAL: Limiting all flavored ENDS to being sold in “**age-restricted, in-person locations.**”
 - *Except* tobacco, menthol, mint.
 - Including all hardware and devices.
- Also allowed where establishment creates area that adequately prevents entry of persons under the age of 18 and the products are not visible or accessible to underage persons.

2.

Restrictions on Brick & Mortar Retail Sales of Flavored ENDS

- Is revisiting compliance policy as it applies to flavored vapor products (*except: tobacco, mint, menthol*) sold in **non-age-restricted venues**.
- Indication that FDA could narrow policy for products on market 8/8/2016, prohibiting marketing of these products under certain conditions (absent premarket authorization).

2.

Restrictions on Brick & Mortar Retail Sales of Flavored ENDS

- FDA is “not revisiting its compliance policy with respect to ENDS products sold exclusively in age-restricted locations.”
- Example 1: Stand-alone retailers that properly age-gate.
- Example 2: Retailer creates area that prevents entry to persons under the age of 18 & the products are not visible or accessible to underage persons.

2.

Restrictions on
Brick & Mortar
Retail Sales of
Flavored ENDS

- No timeline on when policy may issue or when it may take effect.
- Indicated it would be at least 90 days.
- Encouraged manufacturers to voluntarily act in interim.

3.

Best Practices /
Restrictions for
Online Sales of
Certain Flavored
Products

- Revisiting compliance policy for all flavored ENDS products (*except* tobacco, mint, menthol) but not banning online sales.
- FDA will “curtail” those sales online that do not have “**heightened age verification processes.**”
- FDA intends to publish “best practices” to assist compliance.

4.
Enhanced
Marketing
Enforcement

- Warning Letters re: Inappropriate Marketing of Products
- FDA will continue to pursue removal from the market products allegedly marketed to children or appealing to youth, e.g., those using popular children's cartoon characters or brands of candy).



Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 29, 2018

VIA UPS and Electronic Mail

Christopher M. Davis
Chief Executive Officer
Electric Lotus, LLC
1740 Howard Place
Redlands, CA 92373
chris@electriclotus.com
info@electriclotus.com

WARNING LETTER

Dear Mr. Davis:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) has reviewed your submissions to the FDA, our inspection records, and your website, <https://www.elwholesale.com>, and determined that Electric Lotus, LLC manufactures and distributes e-liquid products for commercial distribution in the United States, and that the e-liquid products listed on your website are manufactured and offered for sale or distribution to customers in the United States. Under section 201(n) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(n)), as amended by the Family Smoking Prevention and Tobacco Control Act, these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including e-liquids, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)).



November 29, 2018: Enforcement Letter



VTA Position on FDA Actions

- In meetings with FDA and other federal agencies, VTA has stated:
 - ANPRM: Flavors are essential to FDA's strategic goals
 - Quitting with vapor products is highly individualized
 - Core issue is marketing; not flavors



VTA Position on FDA Actions



MARKETING STANDARDS FOR MEMBERSHIP

The Vapor Technology Association (VTA) is the leading national trade association in the electronic cigarette and vapor product industry. VTA represents the manufacturers, wholesalers, distributors, vape shop owners, small business owners and entrepreneurs who have developed innovative and quality vapor products, providing adult consumers with a safer alternative to traditional combustible products. VTA and its members are leaders in the vapor community, promoting small businesses and job growth, responsible public policies and regulations, and a high standard of safety within the industry.

To continue to promote high standards, VTA's Board of Directors has developed and adopted these Marketing Standards for Membership.

Released December 2017

- To that end, VTA promotes:
 - VTA Marketing Standards
 - Responsible age verification practices both online and in brick-and-mortar locations
 - Importance of flavors to smokers moving away from combustible cigarettes

FTC Meeting

- Met with Consumer Protection at FTC on November 26, 2018
- Introduced FTC to VTA Marketing Standards and solicited ideas for improvements
- Commended FTC for its work with FDA to focus on limiting inappropriate marketing practices



VTA Position on FDA Actions

- Limiting access to flavors for adult smokers.
- Continuing to allow flavored products on the market in the face of heavy media and political scrutiny.
- Increased scrutiny on inappropriate marketing practices.
- Increased enforcement against unauthorized products.



VAPOR TECHNOLOGY ASSOCIATION

ANPRM on Flavors VTA Marketing Standards

www.vaportechnology.org