Unanswered Questions about the FDA’s JUUL Enforcement Blitz
LEGAL TECHNICAL ASSISTANCE

- Legal Research
- Policy Development, Implementation, Defense
- Publications
- Trainings
- Direct Representation
- Lobby
AGENDA

• The Rise of JUUL
• Background on FDA Retail Enforcement
• The FDA’s Enforcement Blitz
THE RISE OF JUUL
THE RISE OF JUUL

E-Cigarette Market Share

- JUUL
- Reynolds/BAT
- Altria
- Imperial/Fontem/Lorillard
- Logic/JTI
- NJOY

PUBLIC HEALTH LAW CENTER
Tobacco Control Legal Consortium
THE RISE OF JUUL

Monthly E-Cigarette Sales

Nielsen All-Channel Data

Market Total  JUUL
THE RISE OF JUUL

Monthly E-Cigarette Sales

Nielsen All-Channel Data

1/23/2019
THE RISE OF JUUL

Monthly E-Cigarette Sales

Nielsen All-Channel Data

PUBLIC HEALTH LAW CENTER
Tobacco Control Legal Consortium

1/23/2019 10
THE RISE OF JUUL

Monthly E-Cigarette Sales

Market Total  JUUL  Reynolds/BAT  Altria  Imperial/Fontem/Lorillard  Logic/JTI  NJOY

PUBLIC HEALTH LAW CENTER
Tobacco Control Legal Consortium

1/23/2019
FDA ACTION
ENFORCEMENT BLITZ

FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access

Warning letters and civil monetary penalty complaints to retailers are largest coordinated enforcement effort in agency history. FDA requests manufacturers provide plans for mitigating youth sales within 60 days. warna it may restrict flavored e-cigarettes to address youth epidemic.

For Immediate Release

Release

The U.S. Food and Drug Administration today announced a series of federal enforcement and regulatory actions related to the sale and marketing of e-cigarettes to kids. This historic coordinated enforcement effort is the FDA's first

historic coordinated enforcement effort is the FDA's first
# FDA RETAIL ENFORCEMENT REQUIREMENTS FOR RETAILERS

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Cigarettes</th>
<th>Smokeless Tobacco</th>
<th>Cigars</th>
<th>E-Cigarettes &amp; Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum legal sales of 18 and age verification under 27</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Prohibition on vending machine sales</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
</tr>
<tr>
<td>Prohibition on self-service displays</td>
<td>Allowed in adult-only facilities</td>
<td>Allowed in adult-only facilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum package requirements</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prohibition on breaking packages by retailers</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Prohibition on free samples</td>
<td>✔️</td>
<td>Allowed in qualified adult-only facility</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Prohibition on characterizing flavors</td>
<td>Menthol and tobacco allowed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FDA RETAIL ENFORCEMENT
THE FEDERAL FISCAL YEAR

October 1, 2017

Fiscal Year

September 30, 2018
### FDA Tobacco Retail Inspection Contracts

FDA issues contracts to assist with compliance check inspections of retail establishments. FDA has a goal of establishing a contract, where feasible, with every U.S. State and Territory, but some States and Territories, for a variety of reasons, have been unable to do so. Therefore, FDA has awarded contracts to third-party entities that are able to hire commissionable inspectors to do compliance check inspections of tobacco retailers in those states and territories where FDA has not been able to contract with a state agency. FDA has further expanded this program by awarding retail inspection contracts to Tribes to conduct retail inspections within their jurisdictions. In addition, FDA may also conduct its own investigations using FDA personnel.

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Contractor</th>
<th>Date of Initial Award</th>
<th>Most Recent Contract Start Date</th>
<th>Most Recent Award Amount</th>
<th>Total Awarded To Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>Alabama Department of Public Health</td>
<td>6/24/2010</td>
<td>9/30/2018</td>
<td>$1,328,880</td>
<td>$12,204,398</td>
</tr>
<tr>
<td>Alaska</td>
<td>Information Systems and Networks Corporation</td>
<td>9/4/2014</td>
<td>9/19/2018</td>
<td>$255,768</td>
<td>$1,816,667</td>
</tr>
<tr>
<td>American Samoa</td>
<td>American Samoa Department of Human and Social Services</td>
<td>9/18/2014</td>
<td>9/30/2018</td>
<td>$147,495</td>
<td>$889,330</td>
</tr>
<tr>
<td>Arizona</td>
<td>Arizona Department of Health Services</td>
<td>9/10/2010</td>
<td>9/30/2018</td>
<td>$351,113</td>
<td>$5,224,268</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Arkansas Tobacco Control Board</td>
<td>9/30/2010</td>
<td>9/30/2018</td>
<td>$689,338</td>
<td>$7,149,003</td>
</tr>
<tr>
<td>California</td>
<td>California Department of Public Health</td>
<td>9/8/2011</td>
<td>9/30/2018</td>
<td>$5,134,174</td>
<td>$28,450,100</td>
</tr>
<tr>
<td>Colorado</td>
<td>Colorado Department of Public Health and Environment</td>
<td>9/30/2010</td>
<td>9/30/2018</td>
<td>$1,496,516</td>
<td>$10,308,544</td>
</tr>
<tr>
<td>Delaware</td>
<td>Information Systems and Networks Corporation</td>
<td>9/19/2011</td>
<td>9/17/2018</td>
<td>$499,642</td>
<td>$1,425,977</td>
</tr>
<tr>
<td>Florida</td>
<td>Information Systems and Networks Corporation</td>
<td>4/1/2014</td>
<td>9/30/2018</td>
<td>$917,927</td>
<td>$8,206,274</td>
</tr>
<tr>
<td>Georgia</td>
<td>Georgia Department of Revenue</td>
<td>9/12/2011</td>
<td>7/23/2018</td>
<td>$618,743</td>
<td>$4,027,818</td>
</tr>
<tr>
<td>Guam</td>
<td>Guam Department of Administration</td>
<td>9/19/2012</td>
<td>9/30/2018</td>
<td>$250,159</td>
<td>$1,580,085</td>
</tr>
</tbody>
</table>

https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm228914.htm
# FDA RETAIL ENFORCEMENT

## REPEATED VIOLATIONS

<table>
<thead>
<tr>
<th>Number of Violations</th>
<th>Timeframe</th>
<th>Possible Enforcement Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Warning Letter</td>
</tr>
<tr>
<td>2</td>
<td>Within 12 months</td>
<td>$285 penalty</td>
</tr>
<tr>
<td>3</td>
<td>Within 24 months</td>
<td>$570 penalty</td>
</tr>
<tr>
<td>4</td>
<td>Within 24 months</td>
<td>$2,282 penalty</td>
</tr>
<tr>
<td>5</td>
<td>Within 36 months</td>
<td>$5,705 penalty</td>
</tr>
<tr>
<td>6</td>
<td>Within 48 months</td>
<td>$11,410 penalty</td>
</tr>
</tbody>
</table>
FDA RETAIL ENFORCEMENT
DATA SOURCES

https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm
FDA RETAIL ENFORCEMENT

DATA SOURCES

https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm
FDA RETAIL ENFORCEMENT
DATA SOURCES

https://www.fda.gov/AboutFDA/Transparency/track/default.htm
FDA ENFORCEMENT BLITZ
DATA SOURCES

Warning Letters and Civil Money Penalties Issued to Retailers for Selling JUUL and Other E-Cigarettes to Minors

June 2018 – September 2018

In the largest coordinated enforcement effort in the FDA's history, the agency issued more than 1,300 warning letters and civil money penalty complaints (CMPS) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide undercover blitz of brick-and-mortar and online stores this summer.

- One-sample warning letter (PDF - 166 KB)
- Retailers who received 1,300+ warning letters and civil money penalty complaints (CMPS)

April 2018 – June 2018

FDA issued warning letters (PDF) and civil money penalties (CMPS) in April - June 2018 as part of a concerted effort to ensure youth are not able to access these products. These retailers sold e-cigarettes—including JUUL products—to minors.

<table>
<thead>
<tr>
<th>Retailer</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Date Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living Hometown Market</td>
<td>462 U.S. Route 202</td>
<td>Ringo</td>
<td>NH</td>
<td>03861</td>
<td>05/06/2018 (CMPS)</td>
</tr>
<tr>
<td>Adam's Smokas and Gifts</td>
<td>5370 West Cheyenne Avenue, Suite 100</td>
<td>Las Vegas</td>
<td>NV</td>
<td>89129</td>
<td>06/06/2018 (CMPS)</td>
</tr>
<tr>
<td>Skipo's Vape and Tobacco Shop</td>
<td>3450 Kildea Farm Road Suite 154</td>
<td>Cary</td>
<td>NC</td>
<td>27518</td>
<td>05/10/2018 (Warning)</td>
</tr>
<tr>
<td>AM PM / Arco</td>
<td>3922 Fruitvale Boulevard</td>
<td>Yakima</td>
<td>WA</td>
<td>98902</td>
<td>05/03/2018 (CMPS)</td>
</tr>
</tbody>
</table>
# FDA ENFORCEMENT BLITZ

## BLITZ TIMING

<table>
<thead>
<tr>
<th>Month</th>
<th>Warning Letter</th>
<th>Fines</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2018</td>
<td>43</td>
<td>3</td>
<td>46</td>
</tr>
<tr>
<td>May 2018</td>
<td>13</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>June 2018</td>
<td>59</td>
<td>11</td>
<td>70</td>
</tr>
<tr>
<td>July 2018</td>
<td>418</td>
<td>61</td>
<td>479</td>
</tr>
<tr>
<td>August 2018</td>
<td>616</td>
<td>59</td>
<td>675</td>
</tr>
<tr>
<td>September 2018</td>
<td>76</td>
<td>2</td>
<td>78</td>
</tr>
<tr>
<td>Total</td>
<td>1,225</td>
<td>137</td>
<td>1,362</td>
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</table>
FDA ENFORCEMENT BLITZ
INSPECTIONS DECREASE

Retail Inspections by Fiscal Year

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2011</td>
<td>20,000</td>
</tr>
<tr>
<td>FY 2012</td>
<td>40,000</td>
</tr>
<tr>
<td>FY 2013</td>
<td>60,000</td>
</tr>
<tr>
<td>FY 2014</td>
<td>80,000</td>
</tr>
<tr>
<td>FY 2015</td>
<td>100,000</td>
</tr>
<tr>
<td>FY 2016</td>
<td>120,000</td>
</tr>
<tr>
<td>FY 2017</td>
<td>140,000</td>
</tr>
<tr>
<td>FY 2018</td>
<td>160,000</td>
</tr>
</tbody>
</table>
FDA ENFORCEMENT BLITZ INSPECTIONS DECREASE
FDA ENFORCEMENT BLITZ
INSPECTIONS DECREASE

Retail Inspections by Month
FDA ENFORCEMENT BLITZ
ENFORCEMENT ACTIONS DECREASE
FDA ENFORCEMENT BLITZ
ENFORCEMENT ACTIONS DECREASE

Cumulative Warning Letters (E-Cigarettes)

Cumulative Fines (E-Cigarettes)
## FY 2017 Monthly Fines by Product

<table>
<thead>
<tr>
<th>Product</th>
<th>E-Cigarettes</th>
<th>Cigars</th>
<th>Cigarettes</th>
<th>Smokeless</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>-</td>
<td>-</td>
<td>385</td>
<td>40</td>
</tr>
<tr>
<td>November</td>
<td>-</td>
<td>-</td>
<td>388</td>
<td>21</td>
</tr>
<tr>
<td>December</td>
<td>-</td>
<td>-</td>
<td>373</td>
<td>32</td>
</tr>
<tr>
<td>January</td>
<td>-</td>
<td>-</td>
<td>390</td>
<td>51</td>
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<tr>
<td>February</td>
<td>-</td>
<td>-</td>
<td>509</td>
<td>49</td>
</tr>
<tr>
<td>March</td>
<td>-</td>
<td>-</td>
<td>609</td>
<td>60</td>
</tr>
<tr>
<td>April</td>
<td>1</td>
<td>5</td>
<td>509</td>
<td>64</td>
</tr>
<tr>
<td>May</td>
<td>2</td>
<td>4</td>
<td>578</td>
<td>66</td>
</tr>
<tr>
<td>June</td>
<td>7</td>
<td>9</td>
<td>564</td>
<td>65</td>
</tr>
<tr>
<td>July</td>
<td>130</td>
<td>216</td>
<td>134</td>
<td>14</td>
</tr>
<tr>
<td>August</td>
<td>75</td>
<td>162</td>
<td>312</td>
<td>33</td>
</tr>
<tr>
<td>September</td>
<td>73</td>
<td>129</td>
<td>256</td>
<td>29</td>
</tr>
</tbody>
</table>
FDA ENFORCEMENT BLITZ
ENFORCEMENT ACTIONS DECREASE

Cumulative Warning Letters (E-Cigarettes)

Cumulative Fines (E-Cigarettes)
FDA ENFORCEMENT BLITZ
ENFORCEMENT ACTIONS DECREASE

Cumulative Warning Letters (E-Cigarettes)

Cumulative Fines (E-Cigarettes)

2017 2018

PUBLIC HEALTH LAW CENTER
Tobacco Control Legal Consortium

1/23/2019 30
FDA ENFORCEMENT BLITZ
E-CIGARETTE WARNING LETTERS

Monthly E-Cigarette Warning Letters

- Warning Letters (2017)
- Warning Letters (2018)

1/23/2019
<table>
<thead>
<tr>
<th></th>
<th>FY 2017</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cigarettes</td>
<td>Smokeless</td>
</tr>
<tr>
<td>October</td>
<td>34.46</td>
<td>34.27</td>
</tr>
<tr>
<td>November</td>
<td>23.08</td>
<td>26.59</td>
</tr>
<tr>
<td>December</td>
<td>19.63</td>
<td>18.18</td>
</tr>
<tr>
<td>January</td>
<td>18.35</td>
<td>15.23</td>
</tr>
<tr>
<td>March</td>
<td>25.34</td>
<td>21.45</td>
</tr>
<tr>
<td>April</td>
<td>21.38</td>
<td>23.09</td>
</tr>
<tr>
<td>May</td>
<td>29.49</td>
<td>19.60</td>
</tr>
<tr>
<td>June</td>
<td>30.84</td>
<td>24.60</td>
</tr>
<tr>
<td>July</td>
<td>38.58</td>
<td>33.18</td>
</tr>
<tr>
<td>August</td>
<td>26.09</td>
<td>27.14</td>
</tr>
<tr>
<td>September</td>
<td>28.90</td>
<td>25.82</td>
</tr>
</tbody>
</table>
Monthly Enforcement Actions by Product Fiscal Years 2017 & 2018

- E-Cigarettes (2017)
- Cigars (2017)
- Cigarettes (2017)
- Smokeless (2017)

- E-Cigarettes (2018)
- Cigars (2018)
- Cigarettes (2018)
- Smokeless (2018)
FDA ENFORCEMENT BLITZ
ENFORCEMENT COMPARISON

Monthly Enforcement Actions by Product Fiscal Years 2017 & 2018

**FDA ENFORCEMENT BLITZ**

**ENFORCEMENT COMPARISON**

Monthly Enforcement Actions by Product Fiscal Years 2017 & 2018

- E-Cigarettes (2017)
- Cigars (2017)
- Cigarettes (2017)
- Smokeless (2017)

- E-Cigarettes (2018)
- Cigars (2018)
- Cigarettes (2018)
- Smokeless (2018)

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1/23/2019 35
FDA ENFORCEMENT BLITZ
ENFORCEMENT COMPARISON

Monthly Enforcement Actions by Product Fiscal Years 2017 & 2018
FDA ENFORCEMENT BLITZ
FOCUS ON JUUL

FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use

Efforts include a historic action against more than 1,300 retailers and five major manufacturers for their roles perpetuating youth access

Today, the U.S. Food and Drug Administration announced a series of critical and historic enforcement actions related to the sale and marketing of e-cigarettes to kids. In the largest coordinated enforcement effort in the FDA’s history, the agency issued more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL or other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores this summer. As a result of these violations and other indications that e-cigarette use among youth has hit epidemic proportions, FDA Commissioner Scott Gottlieb, M.D. signaled that the agency intends to take new and significant steps to address this challenge in a speech at the agency’s headquarters.

“In the coming weeks, we’ll take additional action under our Youth Tobacco Prevention Plan to immediately address the youth access to, and the appeal of, these products,” said Gottlieb. “Today, we asked five e-cigarette manufacturers to put forward plans to immediately and substantially reverse these trends or face a potential decision by the FDA to reconsider extending the compliance dates for submission of premarket applications.”

Those five national brands—Juul, Vuse, MarkTen XL, Blu e-cigs, and Logic—collectively comprise over 97% of the $2.5 billion e-cigarette market in the United States and made up the majority of the products illegally sold to minors as part of the blitz. The agency is asking each company to submit to FDA within 60 days plans describing how they will address the widespread youth use of their products.

If the companies fail to do so, or if the plans do not appropriately address the issue, the FDA will consider whether it would be appropriate to revisit the current policy that results in these products remaining on the market without a marketing order from the agency. This could mean requiring these brands to remove some or all of their flavored products that may
FDA ENFORCEMENT BLITZ
FOCUS ON JUUL?

Juul Blitz Enforcement Actions by Company

- 45.15% Vuse
- 23.15% Blu/MyBlu
- 17.08% JUUL
- 10.15% Other
- 4.46% MarkTen
THE RISE OF JUUL
NO END IN SIGHT

Monthly E-Cigarette Sales

- $50.00
- $100.00
- $150.00
- $200.00
- $250.00
- $300.00
- $350.00

Nielsen All-Channel Data

- Deeming rule takes effect (FDA begins regulating JUUL)
- FDA announces new regulatory plan for tobacco products and delays premarket review deadlines
- FDA requests marketing documents from JUUL
- FDA raids JUUL's HQ
- Class-action lawsuit filed against JUUL
- Altria buys a 35% stake in JUUL
- Surgeon General issues advisory

Retail Blitz

1/23/2019
THE RISE OF JUUL
NO END IN SIGHT

Monthly E-Cigarette Sales

Nielsen All-Channel Data

Market Total  JUUL

13.4%  16.0%
11.3%  11.7%
20.8%

1/23/2019
FUTURE WEBINAR
SAVE THE DATE

The FDA’s Tools to Tackle the JUUL Epidemic

February 26, 2019
12:00 pm CST
CONTACT US

651.290.7506

publichealthlawcenter@mitchellhamline.edu

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@phealthlawctr

facebook.com/publichealthlawcenter