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AN UPDATE ON FDA'S COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

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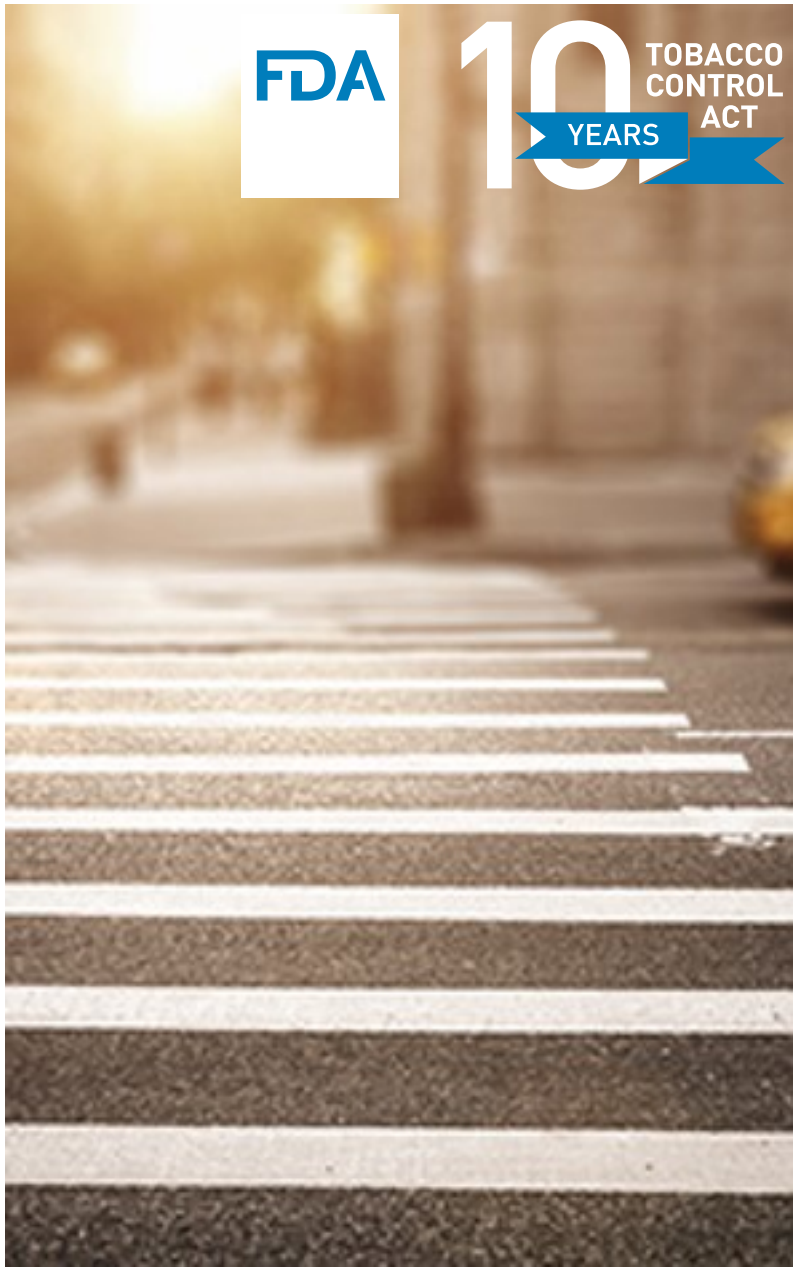
May 2, 2019

CENTER FOR TOBACCO PRODUCTS

AGENDA

- FDA's Comprehensive Plan for Tobacco and Nicotine Regulation
  - Regulatory Policies on Addiction, Appeal & Cessation
  - Youth Tobacco Prevention Plan
  - Science-Based Review of Tobacco Products
- Clarifying Rules of the Road and Other Complementary Efforts
- Questions



FDA'S COMPREHENSIVE REGULATORY PLAN

FDA'S COMPREHENSIVE REGULATORY PLAN

The efforts fall under several categories:

1) Regulatory Policies on Addiction, Appeal & Cessation

2) Youth Tobacco Prevention Plan
   - Access
   - Marketing
   - Education

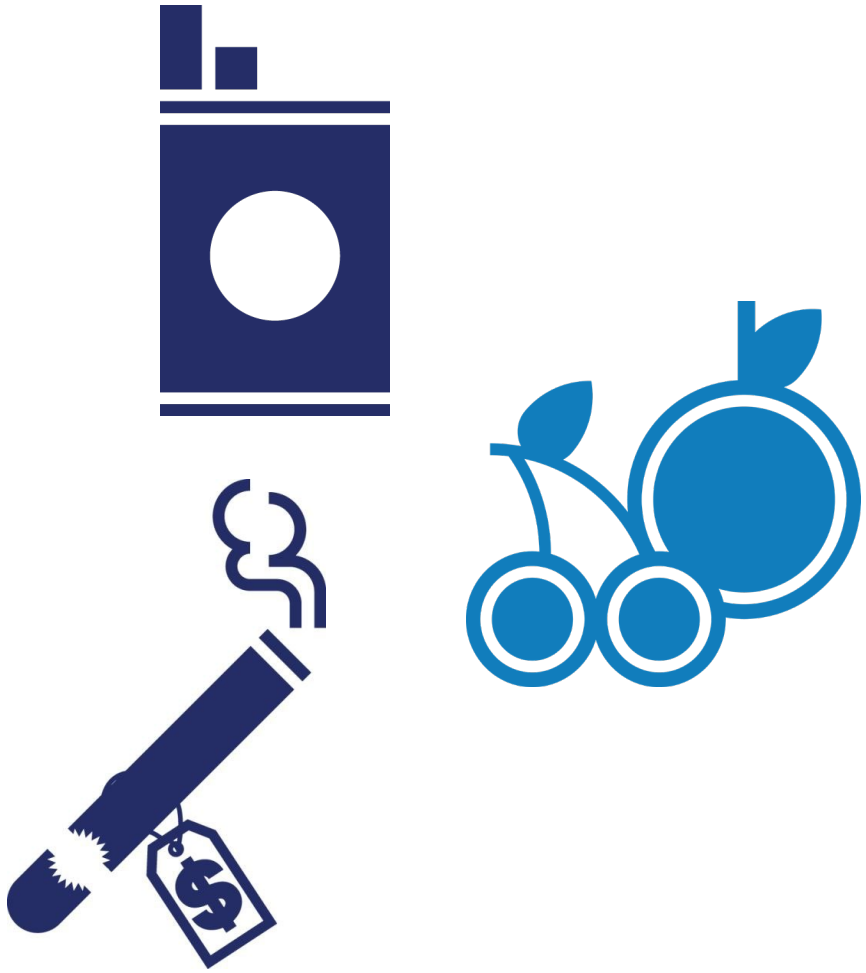
3) Science-Based Review of Tobacco Products

REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

FDA issued three advance notices of proposed rulemaking in 2018 for public comment:

- **March 15:** *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*
- **March 20:** *Regulation of Flavors in Tobacco Products*
- **March 23:** *Regulation of Premium Cigars*



YOUTH TOBACCO PREVENTION PLAN

YOUTH TOBACCO PREVENTION PLAN OVERVIEW

- The Youth Tobacco Prevention plan has three main strategies:
  - *Preventing youth access*
  - *Curbing the marketing of tobacco products aimed at youth*
  - *Educating teens and their families*

- One major concern is the popularity of products that closely resemble a USB flash drive, have high levels of nicotine, and have emissions that are hard to see
  - These characteristics may facilitate youth use by making products more attractive to youth
  - Several of these products fall under the JUUL brand, but other brands with similar characteristics are emerging
  - Kids may be trying these products and liking them without knowing they contain nicotine

ENFORCEMENT ACTIONS TO ADDRESS YOUTH ACCESS AND MARKETING TO YOUTH

YOUTH TOBACCO PREVENTION PLAN ACTIONS

- In May 2018, issued 17 warning letters to manufacturers, distributors, and retailers for selling e-liquids used in e-cigarettes with labeling and/or advertising that cause them to resemble kid-friendly food products such as juice boxes, candy, cookies, and some included cartoon-like imagery
  - FTC jointly-issued 13 of the letters because Section 5 of the Federal Trade Commission Act prohibits unfair or deceptive advertising

- All 17 companies have stopped selling these products
  - Several of the companies were also cited for illegally selling the products to minors

YOUTH TOBACCO PREVENTION PLAN ACTIONS

- In September 2018, in the largest coordinated enforcement effort in FDA's history, issued more than 1,100 warning letters and 131 civil money penalty complaints to retailers who illegally sold e-cigarette to minors
  - Issued 12 additional warning letters to online retailers for selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly products

- Issued letters to the makers of JUUL, Vuse, MarkTen XL, blu e-cigs and Logic asking the companies to submit plans describing how they will address the widespread youth access and use of their products
  - Letters laid out a few examples of actions the companies could take, including eliminating online sales, removing flavored products from the market until they are reviewed by FDA, and revising current marketing practices to help prevent use by those under the age of 18

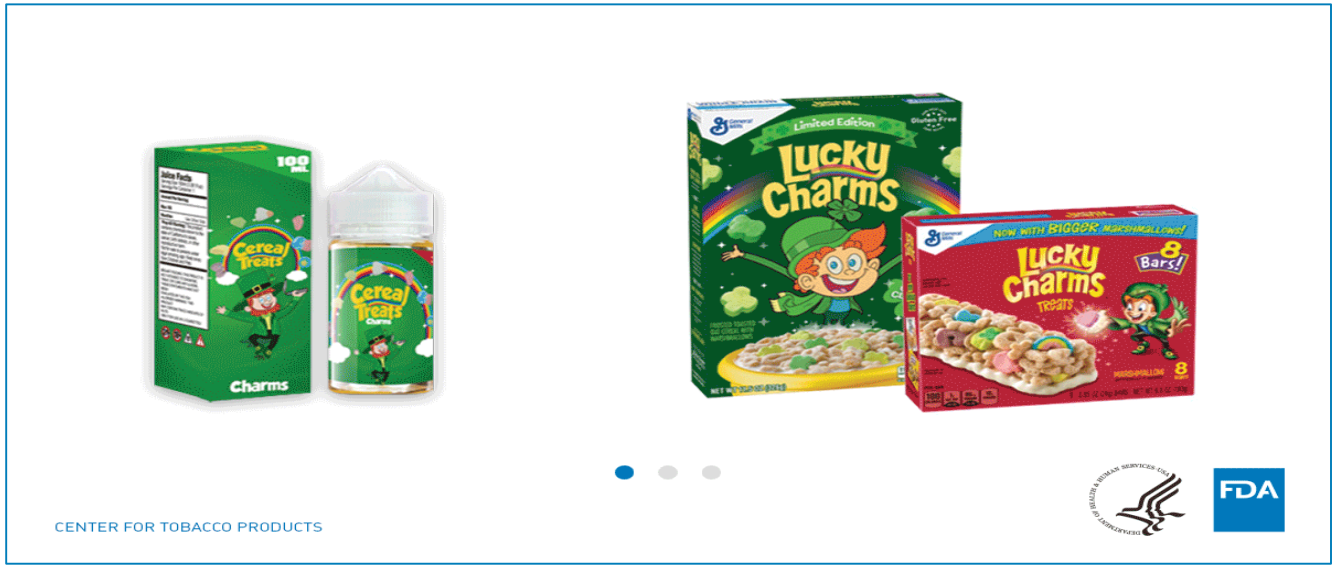
YOUTH TOBACCO PREVENTION PLAN ACTIONS

- On October 11, 2018, issued warning letter to HelloCig Electronic Technology Co. Ltd for various violations, including selling two e-liquids that contain prescription drugs, leading the FDA to determine that the products are unapproved new drugs

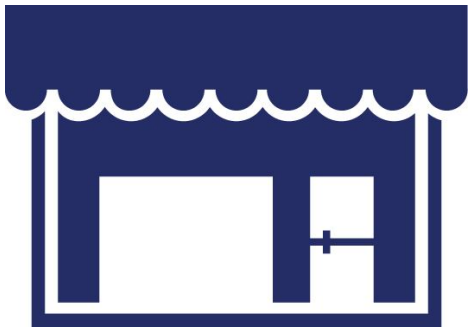
- On October 12, 2018, sent letters to 21 companies as part of investigation of whether 40+ currently marketed e-cigarettes may be subject to enforcement actions because they were not on the market as of August 8, 2016 nor have they received premarket authorizations

YOUTH TOBACCO PREVENTION PLAN ACTIONS

- In November 2018, issued a warning letter to Electric Lotus LLC for selling e-liquids with labeling and/or advertising that cause them to resemble kid-friendly food products such as cereal, candy and peanut butter and jelly
  - Company was also cited for illegally selling products to a minor, for failing to list its products with FDA and for selling e-liquids without the required FDA premarket authorization



YOUTH TOBACCO PREVENTION PLAN ACTIONS



- In February 2019, initiated enforcement action against certain retail locations of Walgreen Co. and Circle K Stores Inc. for repeated violations of restrictions on the sale and distribution of tobacco products, including cigars and menthol cigarettes, to minors
  - Filed complaints seeking No-Tobacco-Sale Orders (NTSO), which seek to bar the retail locations from selling tobacco products for 30 days
  - Walgreens is currently the top violator among pharmacies that sell tobacco products, with 22 percent of the stores inspected having illegally sold tobacco products to minors
- In April 2019, issued letters to Walmart, 7-Eleven, and 10 other chains, whose rates of violations for selling tobacco products to minors exceed 15 percent of their total inspected stores since FDA's retailer compliance check inspection program in 2010
  - Letters request that each company submit within 30 days plans describing how they will address and mitigate illegal sales to minors

YOUTH TOBACCO PREVENTION PLAN ACTIONS

- In April 2019, issued warning letters to two companies, Undisputed Worldwide and EZ Fumes, for manufacturing, selling, and/or distributing nicotine-containing e-liquids with misleading labeling and/or advertising that imitate prescription cough syrup

POLICY ACTION TO ADDRESS YOUTH ACCESS AND MARKETING TO YOUTH

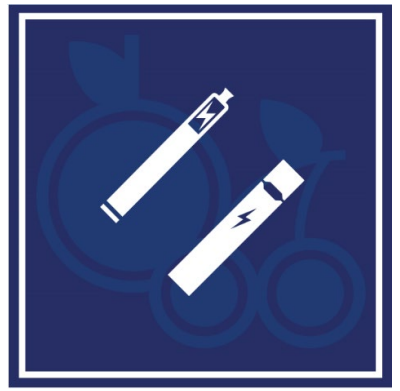
2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED

- 2018 National Youth Tobacco Survey data show an alarming surge in youth e-cigarette use with more than **3.6 million teens currently vaping**
- From 2017 to 2018:
  - Current e-cigarette use **increased 78 percent** among high school students
  - Current e-cigarette use **increased 48 percent** among middle school students
- From 2017 to 2018, among high school students who currently used e-cigarettes
  - Frequent use (on 20 or more days) **increased from 20 percent to 28 percent**
  - Use of flavored tobacco products **increased from 61 percent to 68 percent**

POLICY RESPONSE TO THE SURGE IN YOUTH E-CIGARETTE USE

- In Sept. 2018, FDA announced the agency would be reconsidering all policy options with respect to deemed products to respond to the surge in youth e-cigarette use rates
- In Nov. 2018, FDA announced a framework aimed at preventing youth access to, and appeal of, flavored tobacco products – specifically, e-cigs and cigars
- In March 2019, FDA released draft guidance, "Modifications to Compliance Policy for Certain Deemed Tobacco Products" that outlines policy changes and prioritization of enforcement resources
  - Guidance currently scheduled to take effect 30 days after it is finalized
  - Comments submitted by April 30 will help inform FDA's work on the final guidance

DRAFT GUIDANCE: CHANGES TO COMPLIANCE POLICY - ENDS



- Previously, manufacturers of ENDS on the market as of Aug. 2016 had until 2022 to submit applications for premarket authorization
- **ENDS policy change**: Flavored ENDS products (other than tobacco-, mint-, and menthol-flavored ones) and ENDS products that are targeted to minors or likely to promote use of ENDS by minors, would be subject to enforcement beginning 30 days after guidance is finalized
- Enforcement of this policy change will be prioritized by the following products:
  - Those that are offered for sale in ways that pose a greater risk for minors to access them
  - Those that are targeted to minors or likely to promote use of ENDS by minors
  - Those that are offered for sale in the US, without the manufacturer submitting applications for premarket authorization by Aug. 8, 2021

DRAFT GUIDANCE: CHANGES TO COMPLIANCE POLICY – FLAVORED CIGAR

- Previously, manufacturers of new cigars on the market as of Aug. 2016 had until 2021 to submit applications for premarket authorization
- **Cigar policy change**: Any new flavored cigars (other than tobacco-flavored) on the market as of Aug. 2016, and meet the definition of a new tobacco product, would be subject to enforcement beginning 30 days after guidance is finalized
- Products would have to receive premarket authorization to be re-introduced to the market
- FDA also plans to move forward with a proposed rule to ban all characterizing flavors in cigars

PUBLIC EDUCATION CAMPAIGN

YOUTH TOBACCO PREVENTION PLAN: EDUCATION

- "The Real Cost" Youth E-Cigarette Prevention Campaign is targeted to youth aged 12-17 who have used e-cigarettes or are open to trying them; launched September 2018
- Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, puts them at risk for addiction and other health consequences
- Ads are running online and include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms
- This summer, FDA plans to extend the campaign to include television ads

SCIENCE-BASED REVIEW OF TOBACCO PRODUCTS

REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: PREMARKET TOBACCO APPLICATIONS

- FDA recently authorized the marketing of new tobacco products, under the PMTA pathway, for the IQOS "Tobacco Heating System" manufactured by Phillip Morris Products S.A.
  - An electronic device that heats tobacco-filled sticks wrapped in paper to generate a nicotine-containing aerosol. Referred to as "heat-not-burn" or "heated" tobacco products, they meet the definition of a cigarette in the Food, Drug and Cosmetic Act.
  - Authorized products include the IQOS device, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks
- The authorization of these products for the U.S. market is appropriate for the protection of public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes
  - Includes consideration of risks and benefits to the population as a whole, including users & non-users
  - Stringent marketing restrictions on the products to prevent youth access, use and exposure
  - Postmarket requirements include monitoring market dynamics such as potential youth uptake

REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: MODIFIED RISK APPLICATIONS

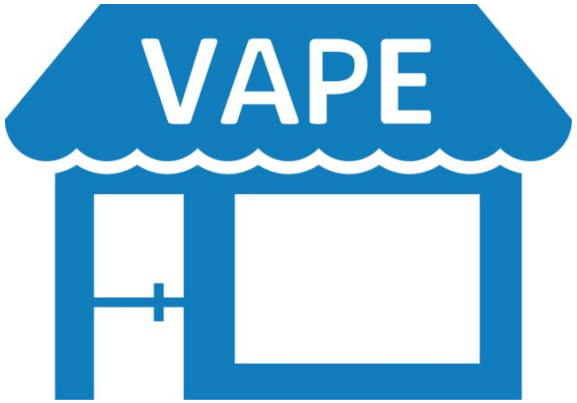
- *IQOS*: In May 2017, FDA filed for scientific review three applications from Philip Morris Products S.A. for its *IQOS* system and three Marlboro *HeatStick* products
  - TPSAC meeting held Jan. 24-25, 2018, comment period closed Feb. 11, 2019
- *Camel Snus*: In Dec. 2017, FDA filed for scientific review applications from R.J. Reynolds Tobacco Company for six smokeless tobacco products
  - TPSAC meeting held Sept. 13-14, 2018, comment period closes May 13, 2019
- *Copenhagen Snuff Fine Cut*: In Sept. 2018, FDA filed for scientific review an application from U.S. Smokeless Tobacco Company for one moist snuff tobacco product
  - TPSAC meeting held Feb. 6-7, 2019, comment period remains open
- *General Snus*: In Dec. 2016, FDA denied one request and deferred on two other requests in Swedish Match North America's MRTP applications for eight smokeless tobacco products
  - TPSAC meeting held Feb. 6-7, 2019, comment period closes May 13, 2019

CLARIFYING RULES OF THE ROAD AND OTHER COMPLEMENTARY EFFORTS

REVISED HPHC REPORTING COMPLIANCE DEADLINE

- On March 8, 2019, FDA released revised guidance on the compliance deadline for reporting Harmful and Potentially Harmful Constituents (HPHCs)
- For newly deemed tobacco products, this revision extends reporting compliance date to six months after the publication date of a final guidance regarding HPHC reporting (nine months after for small tobacco product manufacturers)
- For products entering the market after the publication date of the final guidance, manufacturers must report on HPHCs ninety days prior to marketing the products

VAPE SHOP GUIDANCE



- On March 22, 2019, FDA issued the final guidance "Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops"

- This guidance document is intended to assist retailers who sell newly deemed products and discusses, among other things:
  - Definitions
  - FDA's interpretation of and compliance policy for the label requirements
  - Which activities subject vape shops to certain requirements of the FD&C Act
  - Limited circumstances under which FDA does not intend to enforce compliance

SUBSTANTIAL EQUIVALENCE PROPOSED RULE

- On April 2, 2019, FDA published a proposed rule to establish requirements for the content and format of reports intended to establish the substantial equivalence of a tobacco products and provide information as to how the agency intends to evaluate these submissions
- The proposed rule is intended to provide more clarity to applicants and support efficient and predictable reviews of SE Reports
- The comment period is open through June 17, 2019

IMPROVING EFFICIENCY AND TRANSPARENCY

- FDA continues working on foundational rules and guidances to clarify the “rules of the road,” including but not limited to:
  - Rules for pathway submissions (PMTA, MRTP)
  - Guidance for industry (PMTA for ENDS Final Guidance)
  - Tobacco Product Manufacturing Practices (TPMP)

- Rolling out updates to make the review process more efficient, predictable and transparent while upholding our public health mission

QUESTIONS?

THANK YOU

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