UPDATES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

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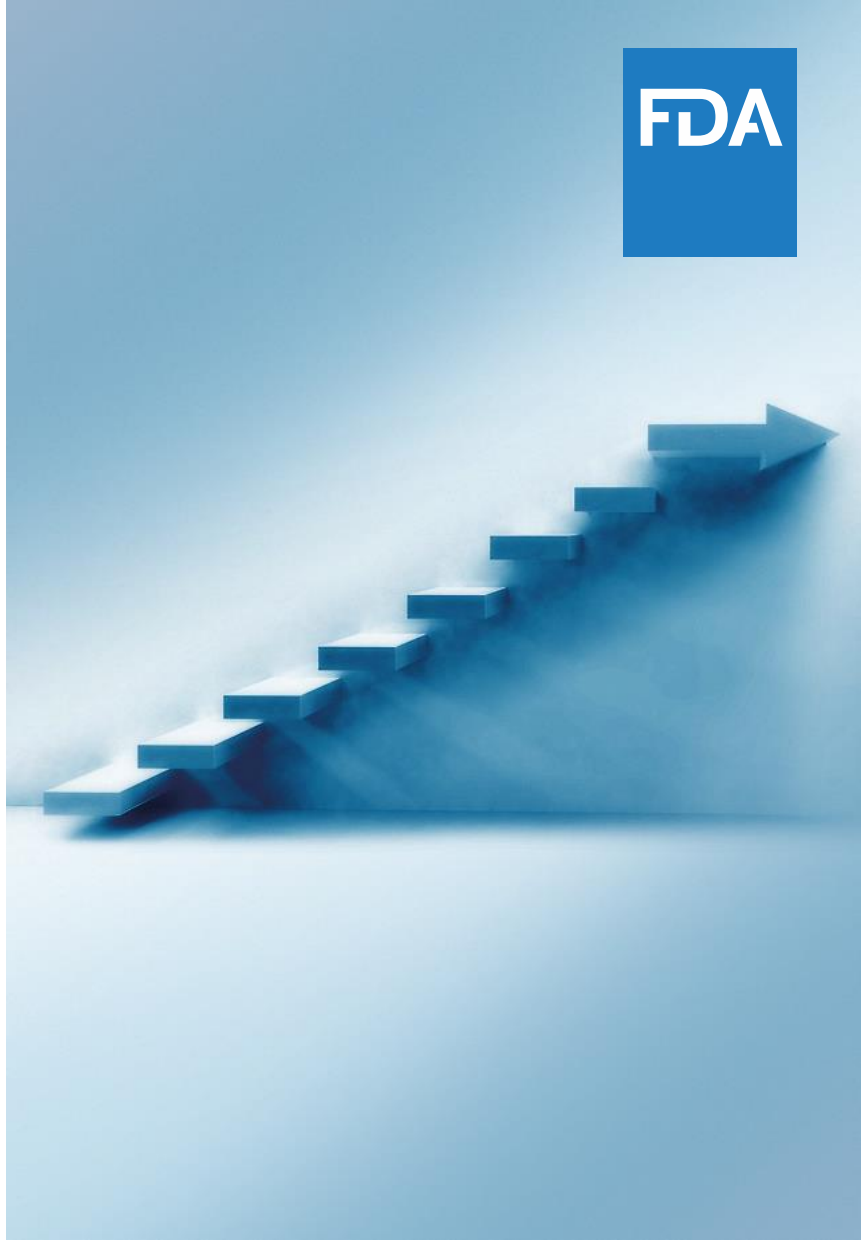
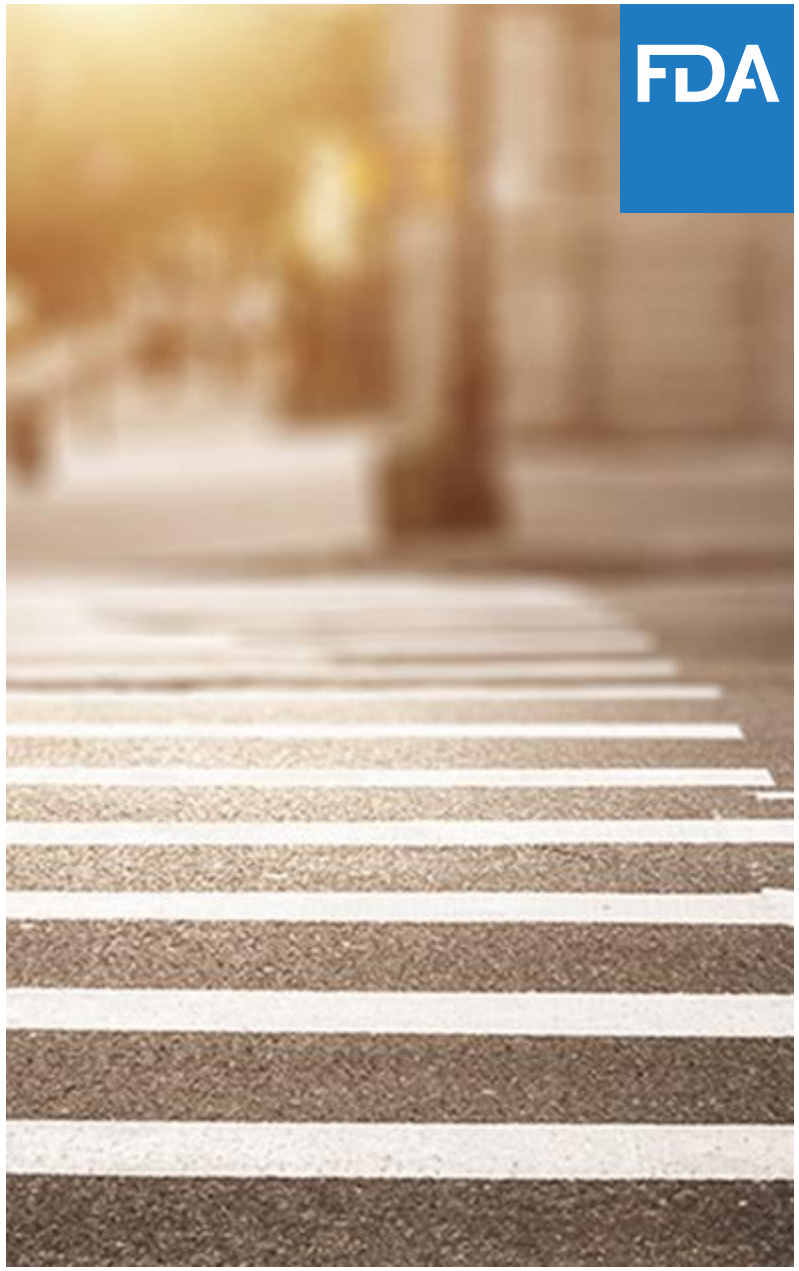


AGENDA

- Programmatic Updates
  - Latest Data on Youth E-Cigarette Use
  - Product Review: Progress on Tobacco Product Application Review
  - Compliance and Enforcement
  - Rules and Guidances
  - Public Education Campaigns
- A New Challenge: Synthetic Nicotine
- Q&A



LATEST DATA ON YOUTH E-CIGARETTE USE

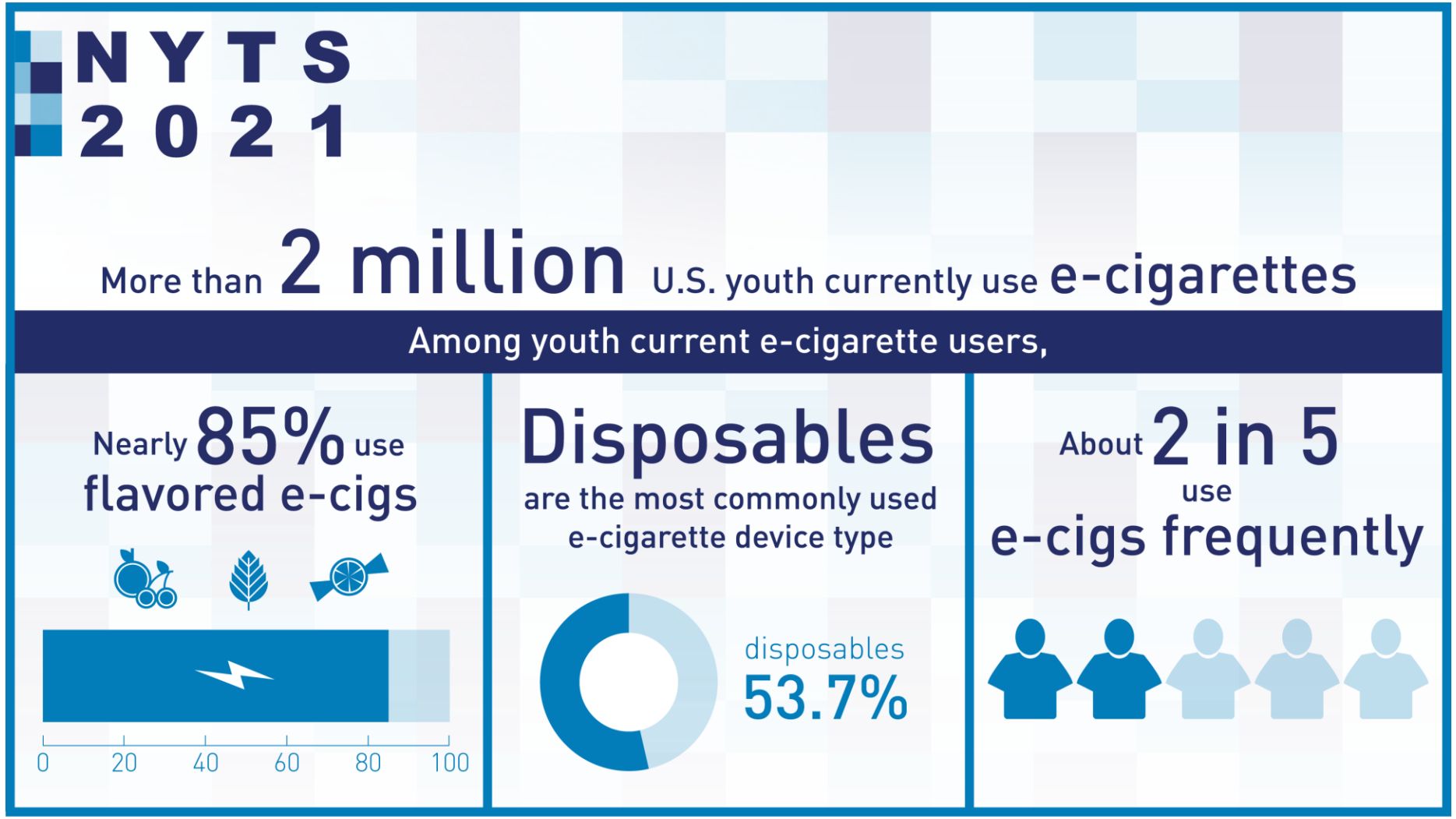
2021 NATIONAL YOUTH TOBACCO SURVEY FINDINGS

On Oct. 1, FDA and CDC released findings from the **2021 National Youth Tobacco Survey** (NYTS) on e-cigarette use among middle and high school students

METHODOLOGICAL CHANGES DUE TO COVID-19

- This NYTS—administered Jan. 18 through May 21, 2021—was the **first to be fully conducted during the COVID-19 pandemic**
- Data were collected using **an online survey** to allow eligible students to participate in the classroom, at home, or in some other place to account for various school settings during this time
- **Different from years before the pandemic**, when the survey was conducted exclusively in the classroom at school
- Because of the changes in the way the survey was conducted this year, 2021 NYTS **results cannot be compared to findings from previous surveys**

2021 NYTS KEY FINDINGS



FLAVORED ENDS PRODUCTS AND YOUTH USE

- Our concern about youth use of e-cigarettes—especially those the data show are **most appealing to, and used by, youth**—remains high

- We continue to address youth use of e-cigarettes through:
  - Premarket review of tobacco product applications
  - Compliance and enforcement efforts
  - Public education campaigns

PRODUCT REVIEW: PROGRESS ON TOBACCO PRODUCT APPLICATION REVIEW

FDA'S TOBACCO AUTHORITIES

- The Tobacco Control Act—passed in 2009—gave FDA immediate authority to regulate cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco

- When FDA's "Deeming Rule" went into effect on Aug. 8, 2016, **FDA's authority expanded** to cover e-cigarettes and all other electronic nicotine delivery systems (ENDS), cigars, pipe tobacco, nicotine gels, and hookah tobacco

- As a result, deemed products are now subject to the same requirements in the Tobacco Control Act that apply to cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco
  - This includes the requirement that **a new tobacco product must receive premarket authorization** from FDA to be legally marketed

PREMARKET APPLICATIONS

- Applications for premarket review for certain deemed new tobacco products on the market as of Aug. 8, 2016, were required to be submitted to FDA **by Sept. 9, 2020**
  - Per a court ruling issued Aug. 19, 2020, FDA is not enforcing this requirement for premium cigars

- FDA received applications for more than **6.5 million deemed new tobacco products,** most of which were submitted very close to the Sept. 9 deadline

- Most applications were premarket tobacco product applications (PMTAs) for ENDS products, like e-cigarettes, which had never previously been through the FDA review process

REVIEW OF PMTAS

- FDA's job is to assess the applicant's scientific evidence to determine if the marketing of the tobacco product is **"appropriate for the protection of the public health"**

- This means we have to assess the **risks and benefits to the population as a whole**, including:
  - Users and nonusers of the product under review
  - Whether people who currently use any tobacco product would stop
  - Whether nonusers would start

REVIEW PROGRESS

- FDA has taken action **on more than 98% of the over 6.5 million products** in the timely submitted applications. As of Oct. 13, this includes:
  - Completing acceptance review for all applications submitted by the Sept. 9 deadline, which resulted in issuing refuse to accept (RTA) letters to **more than 200,000 applications**
  - Completing filing review for almost all timely submitted PMTAs, including issuing a refuse to file (RTF) letter to a single company for PMTAs associated with **approximately 4.5 million products**
  - Issuing Substantial Equivalence (SE) marketing orders covering more than 120 products
  - Issuing Exemption from SE marketing orders covering more than 230 products
  - Issuing **marketing denial orders** (MDOs) for more than **1 million** non-tobacco flavored ENDS products
  - Issuing marketing granted orders for **3 new tobacco products**

CONSIDERATIONS DURING REVIEW OF NON-TOBACCO FLAVORED ENDS PRODUCTS

- Non-tobacco flavored ENDS products **pose a known and significant risk** with respect to youth appeal, uptake, and use

- **ENDS continue to be the most used type of tobacco product among youth**
  - More than 80% of youth who use ENDS report using a flavored product—with fruit being the most reported flavor type overall, by school level, and across all e-cigarette devices
  - Youth ENDS users are more likely to use flavored ENDS compared with adult END users
  - Studies consistently show that flavors influence youth initiation of ENDS use

CONSIDERATIONS DURING REVIEW OF NON-TOBACCO FLAVORED ENDS PRODUCTS

- Companies who want to continue to market their flavored ENDS products **must have robust and reliable evidence** showing that their products' potential benefit for adult smokers outweighs the significant known risk to youth

- By contrast, **tobacco-flavored ENDS** raise a different set of considerations because they **do not pose the same degree of risk of youth uptake**

AUTHORIZATION OF ENDS PRODUCTS THROUGH THE PMTA PATHWAY

- On Oct. 12, **FDA authorized the marketing of three new tobacco products**, marking the first set of ENDS products ever to be authorized by FDA

- R.J. Reynolds (RJR) Vapor Company submitted data that demonstrates its tobacco-flavored products **could benefit addicted adult smokers** who switch to these products—either completely or with a significant reduction in cigarette consumption—by reducing their exposure to harmful chemicals

- Additionally, FDA considered the risks and benefits to the population as a whole and determined the **potential benefits to smokers outweigh the risk to youth**

- FDA also issued **10 MDOs for RJR's flavored Vuse Solo ENDS products**

PMTA AUTHORIZATION: NEW ORAL TOBACCO PRODUCTS

- On Oct. 19, **FDA authorized the marketing of four oral tobacco products** manufactured by U.S. Smokeless Tobacco Company LLC (USSTC) under the brand name of VERVE®
- These are mint flavored products, containing nicotine, that are chewed and then discarded when the user is finished
- The company submitted data that demonstrates these products **could benefit addicted adult smokers** who switch to them—either completely or with a significant reduction in cigarette consumption—by reducing their exposure to harmful chemicals
- Additionally, research shows a **low likelihood that youth, non-smokers, or former smokers would initiate or reinitiate tobacco use** with these products

REMAINING PENDING APPLICATIONS

- FDA continues to work expeditiously on the remaining applications that were submitted by the court's Sept. 9, 2020, deadline, **many of which are in the final stages of review**
  - The agency has **around 80,000 products** pending that are the subject of timely submitted PMTAs

- FDA continues to review PMTAs for non-tobacco flavored ENDS to determine whether there is sufficient product-specific scientific evidence of a benefit to adult smokers to overcome the risk posed to youth
  - **The scientific review of menthol ENDS raises unique considerations**, and FDA is reviewing every product on a case-by-case basis with the same review standards

- FDA is also reviewing a **smaller number of pending applications under the SE standard** for cigars, pipes, and hookah tobacco

LEGAL CHALLENGES AND APPEALS

- As of Oct. 26, 46 cases filed for judicial review of specific MDO actions (45 pending)
- Dozens of requests for supervisory review of negative actions (under Title 21 of Code of Federal Regulations section 10.75)

COMPLIANCE AND ENFORCEMENT

FDA'S ENFORCEMENT PRIORITIES

- All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion

- As described in FDA's enforcement guidance, we have identified **flavored products that appeal to youth as enforcement priorities**

- **Products for which no application is pending**, including, for example, those with an MDO and those for which no application was submitted, **are among our highest enforcement priorities**

UPDATE ON COMPLIANCE AND ENFORCEMENT

- FDA has been closely monitoring manufacturer, importer, and distributor compliance with the premarket authorization requirement

- Since Jan. 2021, FDA has issued 173 warning letters to firms that collectively have listed **more than 17 million ENDS products** with FDA and did not submit premarket applications for these products

- On Oct. 7, FDA issued warning letters to **22 companies** for unlawfully marketing products that are subject to MDOs and/or RTF determinations on their premarket applications

RULES AND GUIDANCES

PMTA AND SE FINAL RULES

- On Oct. 5, **FDA published two final rules** in the Federal Register for the premarket review of new tobacco products—and they are **effective Nov. 4**

- These foundational rules provide additional information on the **requirements for the content, format, and review** of Premarket Tobacco Product Applications (PMTAs) and Substantial Equivalence (SE) Reports

- Finalizing these rules helps ensure all future PMTAs and SE Reports **contain the basic information FDA needs** to determine whether the new tobacco products meet the relevant premarket requirements to efficiently and effectively implement the Tobacco Control Act

LOOKING AHEAD: PROPOSED PRODUCT STANDARDS

- In April, FDA announced it is working toward issuing **proposed product standards** in Spring 2022. FDA plans to:
  - ban menthol as a characterizing flavor in cigarettes
  - ban all characterizing flavors in cigars
- This decision is based on clear science and evidence establishing the **addictiveness and harm of these products** and builds on important, previous actions that banned other flavored cigarettes in 2009
- These actions will help significantly **reduce youth initiation, increase the chances of smoking cessation** among current smokers, **and address health disparities** experienced by communities of color, low-income populations, and LGBTQ+ individuals

PUBLIC EDUCATION CAMPAIGNS

“THE REAL COST” YOUTH E-CIGARETTE USE PREVENTION CAMPAIGN

- Since 2017, FDA’s award-winning public education campaign **“The Real Cost”** has been prioritizing e-cigarette prevention messaging to address alarming youth vaping rates

- “The Real Cost” Youth E-Cigarette Prevention Campaign reaches **youth aged 12 to 17** who have used e-cigarettes or are open to trying them

- Campaign messages focus on **educating youth** that using e-cigarettes, just like cigarettes, puts them at risk for **addiction and other health consequences**

CAMPAIGN REACH

- Since “The Real Cost” E-Cigarette Prevention effort launched, the campaign has shown effective reach and engagement results—**reaching up to 85% of all teens** nationwide through paid media messages

- Across social media, FDA has engaged teen audiences with more than 3.9 million likes, more than 355,000 shares, and more than 90,000 comments—with **10% of comments coming from teens asking for help and resources to quit vaping**

- FDA also collaborated with the National Cancer Institute to develop **vaping cessation content for teens on Teen.SmokeFree.gov**
  - Since the content launched in 2019, there have been more than **2 million page views**
  - Visitors spend an average of **4 minutes per page** to learn how to quit vaping, manage nicotine withdrawal, and deal with stress and anxiety

A NEW CHALLENGE: SYNTHETIC NICOTINE

A RISE IN SYNTHETIC NICOTINE

- Increasing number of ENDS products that **use, or claim to use, synthetic nicotine** instead of nicotine derived from tobacco
  - Includes Puff Bar, reported in the 2021 NYTS as the most popular brand among youth e-cigarette users

- To try to avoid FDA regulation and evade enforcement, several companies that received MDOs are publicly saying they **are switching to synthetic nicotine** to keep their products on the market

Vapor Salon
August 26 ·

> "**VaporSalon is switching to TOBACCO FREE NICOTINE** on Friday, 8/27/2021. … **F*** the FDA** and their over-reaching over-burdensome regulations that small businesses were never ever going to be successful in completing and they knew that from the start."

KEY CHALLENGES WITH SYNTHETIC NICOTINE

- The definition of “tobacco product” includes **any product made or derived from tobacco**, including a component, part, or accessory of a tobacco product

- E-liquids that do not contain nicotine or other substances made or derived from tobacco **may still be components or parts of tobacco products and, therefore, subject to FDA's tobacco control authorities**

- FDA intends to make these determinations on a case-by-case basis, based on the totality of the circumstances

KEY CHALLENGES WITH SYNTHETIC NICOTINE

- It's becoming **more difficult to test and differentiate** tobacco-derived nicotine from synthetic nicotine

- Nicotine has two isomer forms (R- and S-nicotine)
  - Tobacco-derived nicotine is 99% S-nicotine
  - Previous synthetic nicotine formulations were 50/50 nicotine isomers
  - **Newer synthetic nicotine formulations can consist of more than 99% S-nicotine**

- Tobacco-derived nicotine is now readily available as higher quality **U.S. pharmaceutical-grade 99% nicotine,** which no longer contains traditional tobacco agricultural markers like tobacco DNA or tobacco specific nitrosamines – **making it harder to distinguish tobacco-derived nicotine from synthetic**

FDA'S REGULATORY PATH FORWARD

- FDA is very concerned about the implications of **companies attempting to evade regulation** by using synthetic nicotine, particularly as it regards to potential youth ENDS use

- In the short term, the agency is exploring how to best address the growing number of products where the **jurisdiction is under review due to the source of nicotine**

- FDA is also in discussions with Congress about a potential legislative fix

ADDITIONAL FDA PRESENTATION

Matthew R. Holman, Ph.D., Director,

Office of Science, Center for Tobacco Products

1:30 – 2:40 p.m.

- Panel coming up next after the break -

Pre-Market Tobacco Applications (PMTAs):
Recent Decisions and Surveying the Post-Deadline Landscape

CONTACTING/FOLLOWING FDA'S CENTER FOR TOBACCO PRODUCTS

- Report adverse experiences with tobacco products at: https://www.safetyreporting.hhs.gov
- Call us: (877) CTP-1373
- Email us: AskCTP@fda.hhs.gov
- Follow us on Twitter: @FDATOBACCO