UPDATES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

Presented by
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Director, FDA Center for Tobacco Products

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

Looking Back

Programmatic Priorities

Looking Forward
LOOKING BACK
CIGARETTE CONSUMPTION 1900-2020

CURRENT ADULT USE OF TOBACCO PRODUCTS (2020)

- Cigarettes: 12.5%
- E-cigarettes: 3.7%
- Cigars: 3.5%
- Smokeless tobacco: 2.3%
- Pipes: 1.1%

HEALTH DISPARITIES AND CURRENT TOBACCO USE AMONG ADULTS (2020)

CURRENT TOBACCO PRODUCT USE AMONG MIDDLE AND HIGH SCHOOL STUDENTS (2022)

Dashed lines represent electronic data collection and solid lines represent data collection via paper and pencil instrument. The ability to compare results between 2022 and previous survey waves is limited because of methodological changes.

NOTE: Smokeless tobacco use is defined as use of chewing tobacco, snuff, dip, snus, or dissolvable tobacco product on ≥1 day during the past 30 days.

SCIENCE DRIVES DECISIONS

Data

Rulemaking

Compliance

Application Review

Communication & Education
Over 600 CTP-funded research projects from FY10 - FY22

More than 60% of these projects were funded through the NIH

Have resulted in more than 3,600 publications from FY10 - FY22

Of those publications almost 400 publications were published in FY22
Over a quarter of citations referenced in two recent proposed rules were CTP-funded publications

26%

Product Standard for Characterizing Flavors in Cigars:
- 254 peer-reviewed publications cited, of which 73 (29%) were CTP-funded

Tobacco Product Standard for Menthol in Cigarettes:
- 250 peer-reviewed publications cited. Of these, 58 (23%) were CTP-funded
Three scientific assessments were developed and went through FDA’s external peer review process:

- SCIENTIFIC ASSESSMENTS ON ROLE OF MENTHOL IN CIGARETTES AND FLAVORS IN CIGARS
By monitoring and assessing behaviors, attitudes, biomarkers, and health outcomes associated with tobacco use in the United States, the PATH Study helps enhance the evidence base available to inform FDA’s regulatory activities related to tobacco.
PROGRAMMATIC PRIORITIES
PROGRAMMATIC UPDATES

Rules & Guidances

Application Review

Compliance & Enforcement

Public Education
PROGRAMMATIC UPDATES

Rules & Guidances

Application Review

Compliance & Enforcement

Public Education
RULEMAKING PROCESS

- Rule/Regulation Proposed
- Public Comments Considered
- Final Rule Issued
FDA has **proposed product standards** to:

- Prohibit **menthol** as a characterizing flavor in cigarettes
- Prohibit all **characterizing flavors**, except tobacco, in cigars
FDA plans to develop a proposed product standard that would establish a **maximum nicotine level** to reduce the addictiveness of cigarettes and certain other combusted tobacco products.
• Guidance includes FDA’s recommendations on how to perform studies to assess, among other things:
  
  – Individuals’ perceptions of tobacco products
  
  – Understanding of tobacco product information (e.g., labeling, modified risk information)
  
  – Intentions to use tobacco products
PROGRAMMATIC UPDATES

Rules & Guidances

Application Review

Compliance & Enforcement

Public Education
Applications received for about **26 million** products, mostly e-cigarettes.

Action taken on **99%** of the applications, including:

- Marketing authorizations for **23** e-cigarette products
- Refuse to accept letters, refuse to file letters, or marketing denial orders for **Millions** of products
APPLICATION REVIEW STATUS TOTAL: PMTA FY20-23

FY 20-23 Progress

Premarket Tobacco Product Application

Number of Products

<table>
<thead>
<tr>
<th>Acceptance</th>
<th>Filing</th>
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<tr>
<td>Accepted</td>
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- Over 19.5 Million: Accepted
- Over 5 Million: Refused to File
- Over 6.7 Million: Accepted
- Over 1 Million: Refused to File
- Over 1.2 Million: Marketing Denial Order
- Over 30: Marketing Granted Order

Data as of 2/21/2023
APPLICATION REVIEW STATUS TOTAL: SE FY20-23

FY 20-23 Progress

Substantial Equivalence

Number of Products

<table>
<thead>
<tr>
<th>Accepted</th>
<th>Refused to Accept</th>
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<tr>
<td>Over 6,000</td>
<td>Over 2,000</td>
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<th>REVIEW AND ACTION</th>
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<tr>
<td>Over 550</td>
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<td>Over 90</td>
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Substantial Equivalence Order
Not Substantially Equivalent Order

Data as of 2/21/2023
APPLICATION REVIEW STATUS TOTAL: EX FY20-23

FY 20–23 Progress

Exemption Request

Number of Products

- Over 2,000 Accepted
- Over 2,000 Refused to Accept
- Over 750 Substantial Equivalence Order
- Over 100 Not Substantially Equivalent Order

Data as of 2/21/2023
RECENT PREMARKET TOBACCO APPLICATION ACTIONS

- **Marketing Granted (3) and Marketing Denial Orders**
  - R.J Reynolds Vapor Company: Vuse Solo

- **Marketing Granted (8) and Marketing Denial Orders**
  - Logic, LLC: Logic Vapeleaf, Logic Pro, Logic Power

- **Marketing Granted (4) Orders**
  - U.S Smokeless Tobacco Company, LLC: VERVE©

- **Marketing Denial Orders**
  - Fontem, US, LLC: myblu
Recent Premarket Tobacco Application Actions

Marketing Granted (2) and Marketing Denial Orders
NJOY LLC: NJOY Daily

Marketing Denial Orders
Magellan Technology, LLC: Hyde

**Marketing Denial Orders
Logic, LLC: Logic Pro Menthol; Logic Power Menthol

***Marketing Denial Orders
R.J Reynolds Vapor Company: Vuse Vibe Tank Menthol and Vuse Ciro Cartridge Menthol

Marketing Granted (6) and Marketing Denial Orders
R.J Reynolds Vapor Company: Vuse Vibe and Vuse Ciro

*Marketing Denial Orders
JUUL Labs Inc (JUUL System)

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*On July 5, 2022, the Agency issued a stay for this MDO pending its review.
**On December 15, 2022, the U.S. Court of Appeals for the Third Circuit entered a stay pending review of this MDO.
***On January 25, 2023, the United States Court of Appeals for the Fifth Circuit granted a temporary administrative stay of the MDO issued to R.J. Reynolds Vapor Company’s Vuse Vibe menthol e-cigarette product.
PROGRESS ON PMTAS FOR NON-TOBACCO NICOTINE PRODUCTS

> 99%

MORE THAN 8,600 products accepted for review

MORE THAN 925,000 products not accepted for review

*As of Jan 20, 2023*
PROGRAMMATIC UPDATES

Rules & Guidances

Application Review

Compliance & Enforcement

Public Education
CTP COMPLIANCE AND ENFORCEMENT ACTIVITIES

Compliance, Training, Education, and Outreach

Surveillance, Inspections, and Investigations

Enforcement Actions

Industry Compliance
COMPLIANCE & ENFORCEMENT

Manufacturers
- Warning Letters
- Civil Money Penalties
- Recalls
- Seizure
- Injunction
- Criminal Prosecution

Retailers
- Warning Letters
- Civil Money Penalties
- No-Tobacco Sale Order (NTSO)
- Seizure
- Injunction
- Criminal Prosecution
COMPLIANCE AND ENFORCEMENT ACTION: ONLINE INVESTIGATIONS

Through February 10, 2023

>1,200 Warning Letters

issued through online investigations for various tobacco product violations of the Federal Food, Drug, and Cosmetic Act

Online investigations (Manufacturers, Retailers, and Other Entities)
COMPLIANCE AND ENFORCEMENT ACTIONS (AS OF FEB 2023)

Manufacturers

- **Warning Letters**
  - ~800 (OVER 450 FOR ENDS)

- **Civil Money Penalties**
  - 4 (ALL ENDS)

- **Injunctions**
  - 6 (ALL ENDS)
MORE THAN 75 Warning Letters
To manufacturers for marketing non-tobacco nicotine products without the required premarket authorization
On Nov. 16, 2022 FDA issued warning letters to 5 firms for the marketing of 15 different e-cigarette products. The unauthorized products described in the warning letters include e-cigarettes that:

- Are designed to look like toys;
- Feature youth-appealing characters from TV shows, movies, and cartoons;
- Imitate youth appealing food.
On February 22, 2023, FDA filed civil money penalties (CMP) complaints against four tobacco product manufacturers for manufacturing and selling e-liquids without marketing authorization.

This was the first time FDA filed CMP complaints against tobacco product manufacturers to enforce the premarket review requirements for new tobacco products.
INJUNCTIONS: ENDS MANUFACTURERS

- On October 18, 2022, DOJ, on behalf of FDA, filed complaints for permanent injunctions in federal district courts against six e-liquid manufacturers that failed to submit premarket applications for their e-cigarettes and continued to illegally manufacture, sell, and distribute their products.

- These cases represent the first time the FDA initiated injunction proceedings to enforce the premarket review requirements for new tobacco products.
COMPLIANCE & ENFORCEMENT

Manufacturers
- Warning Letters
- Civil Money Penalties
- Recalls
- Seizure
- Injunction
- Criminal Prosecution

Retailers
- Warning Letters
- Civil Money Penalties
- No-Tobacco Sale Order (NTSO)
- Seizure
- Injunction
- Criminal Prosecution
Brick and Mortar Retailer Inspections: OVER 1.3 MILLION

- **WARNING LETTERS:** OVER 120,000 (OVER 18,000 FOR ENDS)
- **CIVIL MONEY PENALTIES:** OVER 27,000 (OVER 2,600 FOR ENDS)
- **NO-TOBACCO-SALE ORDERS:** 220

as of Dec. 2022
MORE THAN 650 Warning Letters
To retailers for illegally selling non-tobacco nicotine products to underage buyers

*As of Feb. 2023*
PROGRAMMATIC UPDATES

Rules & Guidances

Application Review

Compliance & Enforcement

Public Education
TOBACCO PREVENTION CAMPAIGNS

THE REAL COST™

**Prevented up to 587,000** youth ages 11-19 from **trying** cigarettes, half of whom may have become adult smokers

**Will save more than $180,000** for each of the up to 293,500 youth **prevented** from becoming established smokers

**Will save more than $53 Billion** by **reducing** smoking-related cost like, medical care, lost wages, and increased disability
THE REAL COST: NEWEST ADS

“Auctioneer”

“Said Every Smoker Ever”
TOBACCO PREVENTION CAMPAIGNS

Most vapes contain seriously addictive levels of nicotine.
TOBACCO CESSATION RESOURCES

Last time I quit smoking, I failed. I got closer to finishing the job.

Quitting cigarettes isn’t a perfect process.

“Every time you try to quit, you get closer to quitting for good. Keep going at EveryTryCounts.gov.”

Dejar el cigarrillo no es un proceso perfecto.

“No dejé de fumar en mi primer intento, pero sé que no fracasé. Simplemente es parte del proceso.”

Keep going with your quit process at EveryTryCounts.gov.
RESOURCES

- smokefree.gov
- digitalmedia.hhs.gov/tobacco
- everytrycounts.gov
CONTINUUM OF RISK

Formative scientific research is critical to inform any public messaging.

- Continuing research into messaging among adult smokers that nicotine is delivered through products that represent a continuum of risk.
Califf RM, King BA. The Need for a Smoking Cessation “Care Package”. JAMA. 2023;329(3):203–204.
CTP DIRECTOR’S PRIORITIES

- Sound Science
- Stakeholder Engagement
- Communication
- Health Equity
EXTERNA L EVALUATION: REAGAN-UDALL FOUNDATION

- Reagan-Udall Holds Public Listening Sessions
- Reagan-Udall Announces Expert Panel Members
- Reagan-Udall Conducts Evaluation
- Reagan-Udall Releases Evaluation Recommendations
- FDA Releases Plans to Address Recommendations

- July 2022
- August 2022
- September 2022
- October 2022
- November 2022
- December 2022
- January 2023
- February 2023
EXTERNAL EVALUATION PLANNED ACTIONS

- Cross-Cutting
- Science & Application Review
- Regulation & Guidance
- Compliance & Enforcement
- Public Education Campaigns
- Resources
CTP’S RESPONSE (FEBRUARY 2023)
CREATE 5 YEAR STRATEGIC PLAN

OBTAIN PUBLIC INPUT ON PLAN

IMPROVE TRANSPARENCY
• Increase Use of Tobacco Products Scientific Advisory Committee (TPSAC)

• Develop a Clear and Predictable Framework for Application Reviews

• Clarify Substantive Review Processes
• Create a More Effective Approach to Achieve Regulatory Review and Enforcement Goals.
• Establish an Interagency Task Force to Make Enforcement a Priority
• Consider Statutory Changes to Streamline Tobacco Enforcement Processes
• Explore Alternative Approaches to Compliance
• Enhance Communication to Provide Greater Transparency on Compliance and Enforcement
• Ensure Workplan and Goals Reflect New Priorities
• Solicit Broad Input on Public Education Campaigns
RESOURCES

- Improve Abilities to Recruit, Hire, and Retain Personnel to Meet Public Health Mandates
- Pursue Securing User Fees from Each Sector
FDA remains committed to using our regulatory authorities to protect public health

• Research continues to be critical to inform regulatory activities to reduce youth tobacco initiation, reduce tobacco product harms, and encourage tobacco product users to quit.

• The scientific community's contribution is essential. The research conducted touches every aspect of what CTP does.
OTHER CTP PRESENTATIONS AT SRNT

- **Policy Theme Lecture Plenary:** Understanding commercial tobacco use in populations of special relevance: Examination of health equities and tobacco in the Population Assessment of Tobacco and Health (PATH) Study
  - March 3, 2023, 1:45 – 2:45 PM

- **Oral Paper:** Use Patterns of Flavored Non-Cigarette Tobacco Products Among US Adults, 2014 – 2019
  - **Session:** PPS21
  - March 4, 2023, 8:00 AM

- CTP also has 15 posters being presented during the poster session.
QUESTIONS?

Report adverse experiences with tobacco products at:
https://www.safetyreporting.hhs.gov

Call us  (877) CTP-1373

Email us  AskCTP@fda.hhs.gov

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