FDA’S COMPREHENSIVE APPROACH TO TOBACCO PRODUCT REGULATION

AN UPDATE FROM FDA’S CENTER FOR TOBACCO PRODUCTS

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

- Speaker is an employee of the U.S. Government

- Under Section 919 of the Food, Drug, and Cosmetic Act, FDA assesses and collects tobacco user fees from domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigar, and pipe tobacco. These user fees provide funding for FDA’s tobacco regulatory activities.
TOBACCO REGULATION IN THE UNITED STATES

2009
Tobacco Control Act

2016
Deeming Final Rule

2022
Non-Tobacco Nicotine
FDA'S TOBACCO REGULATORY ACTIVITIES

Review tobacco product applications to ensure that new tobacco products meet public health standards.

Ensure tobacco manufacturers and retailers follow the law through surveillance, inspections and enforcement.

FDA's Center for Tobacco Products

Educate the public, especially youth, about the dangers of using tobacco products.

Implement the tobacco control laws through rules & guidances.
CTP RESEARCH PROGRAM

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
TOBACCO CENTERS FOR REGULATORY SCIENCE, FY2018 - 2022

University of Michigan [Ann Arbor, MI]
Roswell Park Cancer Institute Corporation [Buffalo, NY]
Univ. of Vermont & State Agricultural College [Burlington, VT]
Yale University [New Haven, CT]
University of Pennsylvania [Philadelphia, PA]
Virginia Commonwealth University [Richmond, VA]

University of California [San Francisco, CA]
University of Southern California [Los Angeles, CA]
American Heart Association [Dallas, TX]
CTP SURVEILLANCE

PATH
Population Assessment of Tobacco and Health
A collaboration between the NIH and FDA

NYTS
National Youth Tobacco Survey
TIME SENSITIVE DATA COLLECTION OPPORTUNITIES: NIH COOPERATIVE AGREEMENTS

• **Center for Rapid Surveillance of Tobacco (CRST)** will complement traditional data collection methods, making information about changes in the tobacco product marketplace and tobacco use patterns available sooner.

• **Center for Coordination of Analysis, Science, Enhancement, and Logistics (CASEL)** will coordinate an Opportunity Fund to support time-sensitive, rapid response projects to which extramural investigators may apply.
AGENDA

Premarket Review

Product Standards

Compliance & Enforcement

Public Health Education & Resources
PATHWAYS TO MARKET

- Premarket Tobacco Product Application (PMTA)
- Substantial Equivalence (SE) Report
- Exemption from SE Request (EX REQ)
- Pre-Existing Tobacco Product
- Marketing Authorization
WEIGHING THE NET PUBLIC HEALTH IMPACT

“Appropriate for the Protection of the Public Health”
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
MULTI-DISCIPLINARY REVIEW

INDIVIDUAL HEALTH IMPACT

POPULATION HEALTH IMPACT

ENGINEERING

CHEMISTRY

TOXICOLOGY

BEHAVIORAL AND CLINICAL PHARMACOLOGY

MICROBIOLOGY
WEIGHING BEHAVIORAL EVIDENCE FOR FLAVORED ENDS IN PMTA

Robust and Reliable evidence
(e.g. randomized clinical trial, longitudinal cohort)

Participants followed over time

Comparison of tobacco-flavored vs. other flavored products

Product-specific evidence

Outcomes focus on actual behavior
(complete cessation or significant cigarette reduction)
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
RESEARCH IN ACTION

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.
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.
PROGRAMMATIC UPDATES

Premarket Review

Product Standards

Compliance & Enforcement

Public Health Education & Resources
CTP COMPLIANCE AND ENFORCEMENT ACTIVITIES

Compliance, Training, Education, and Outreach

Surveillance, Inspections, and Investigations

Enforcement Actions

Industry Compliance
ENFORCEMENT SCOPE

Manufacturer

Importer

Distributor

Retailer
COMPLIANCE & ENFORCEMENT: MANUFACTURERS

- Recalls
- Seizure
- Civil Money Penalties
- Injunction
- Warning Letters
- Criminal Prosecution
COMPLIANCE & ENFORCEMENT: RETAILERS

- **STOP**
  - No-Tobacco Sale Order (NTSO)
- **$**
  - Civil Money Penalties
- **⚠️**
  - Warning Letters
- **🚫**
  - Seizure
  - Injunction
- **ילים**
  - Criminal Prosecution

Retailers
Through May 2023,

>1,200 Warning Letters

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

- ~800 WARNING LETTERS (OVER 750 FOR ENDS)
- 10 CIVIL MONEY PENALTIES (ALL ENDS)
- 6 INJUNCTIONS (ALL ENDS)

- OVER 126,000 WARNING LETTERS (OVER 20,000 FOR ENDS)
- OVER 29,000 CIVIL MONEY PENALTIES (OVER 3,100 FOR ENDS)
- 221 NO-TOBACCO-SALE ORDERS
FDA ENFORCEMENT AGAINST DISPOSABLE & FLAVORED E-CIGARETTE PRODUCTS
ENFORCEMENT RESOURCES

Compliance Check Inspections of Tobacco Product Retailers
(includes inspection decisions through 05/31/2023)

Search Inspection Decisions

<table>
<thead>
<tr>
<th>Retailer Name</th>
<th>Inspective Outcome</th>
<th>Search Purchaser (SP) Involved</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Warning Letter</td>
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</table>

<table>
<thead>
<tr>
<th>Inspector Name</th>
<th>Date Address</th>
<th>City</th>
<th>Date</th>
<th>Type</th>
<th>Safe to EP</th>
<th>Product Type</th>
<th>Decision Date</th>
<th>Inspection Outcome</th>
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</thead>
<tbody>
<tr>
<td>ZELENONNI</td>
<td>500 N. MAIN ST</td>
<td>FL</td>
<td>04/01/2023</td>
<td>Yes</td>
<td>ENDS</td>
<td>Cigar</td>
<td>05/31/2023</td>
<td>Civil Monetary Penalty</td>
</tr>
<tr>
<td>ZELENONNI</td>
<td>1234 N. AVENUE</td>
<td>MD</td>
<td>04/01/2023</td>
<td>Yes</td>
<td>ENDS</td>
<td>Cigar</td>
<td>05/31/2023</td>
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</tbody>
</table>

Note: The above table is a snapshot of inspection results as of 05/31/2023. For the most up-to-date information, please refer to the official website or contact the FDA directly.
PROGRAMMATIC UPDATES

- Premarket Review
- Product Standards
- Compliance & Enforcement
- Public Health Education & Resources
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 costs like, medical care, lost wages, and increased disability
CONTINUUM OF RISK

- FDA is continuing research into messaging among adult smokers that nicotine is delivered through products that represent a continuum of risk.
- Initial data-driven efforts are underway to assess potential messaging approaches on perceptions about the relative risk of tobacco products – among both intended (i.e. adults who smoke) and unintended (e.g. youth) audiences.

Formative scientific research is critical to inform any public messaging.
SUMMARY

• FDA remains committed to using the full scope of its regulatory authorities to protect public health and makes decisions based on science and evidence establishing the addictiveness and harm of tobacco products.

• CTP leads and collaborates on tobacco regulatory science research.

• CTP supports grants and contracts to generate research to inform the regulation of tobacco products to protect public health.
ACTIVE FUNDING ANNOUNCEMENTS

NIH Tobacco Regulatory Science Program
- Tobacco Regulatory Science (R01)
- Pathway to Independence Award in Tobacco Regulatory Research (K99/R00)
- Mentored Research Scientist Career Development Award in Tobacco Regulatory Research (K01)

FDA
- Support for Conferences and Scientific Meetings (R13)
- Contract opportunities are published through the Federal Business Opportunities website

Funding Opportunities FDA
NIH Tobacco Regulatory Science Program Funding Opportunities
### OTHER RESOURCES

<table>
<thead>
<tr>
<th>FDA CTP Research</th>
<th>NIH Tobacco Regulatory Science Program</th>
<th>Federal Business Opportunities Website</th>
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**July 2023 | Tobacco Online Policy Seminar**
QUESTIONS?

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