

# FDA'S COMPREHENSIVE APPROACH TO TOBACCO PRODUCT REGULATION

*AN UPDATE FROM FDA'S  
CENTER FOR TOBACCO PRODUCTS*

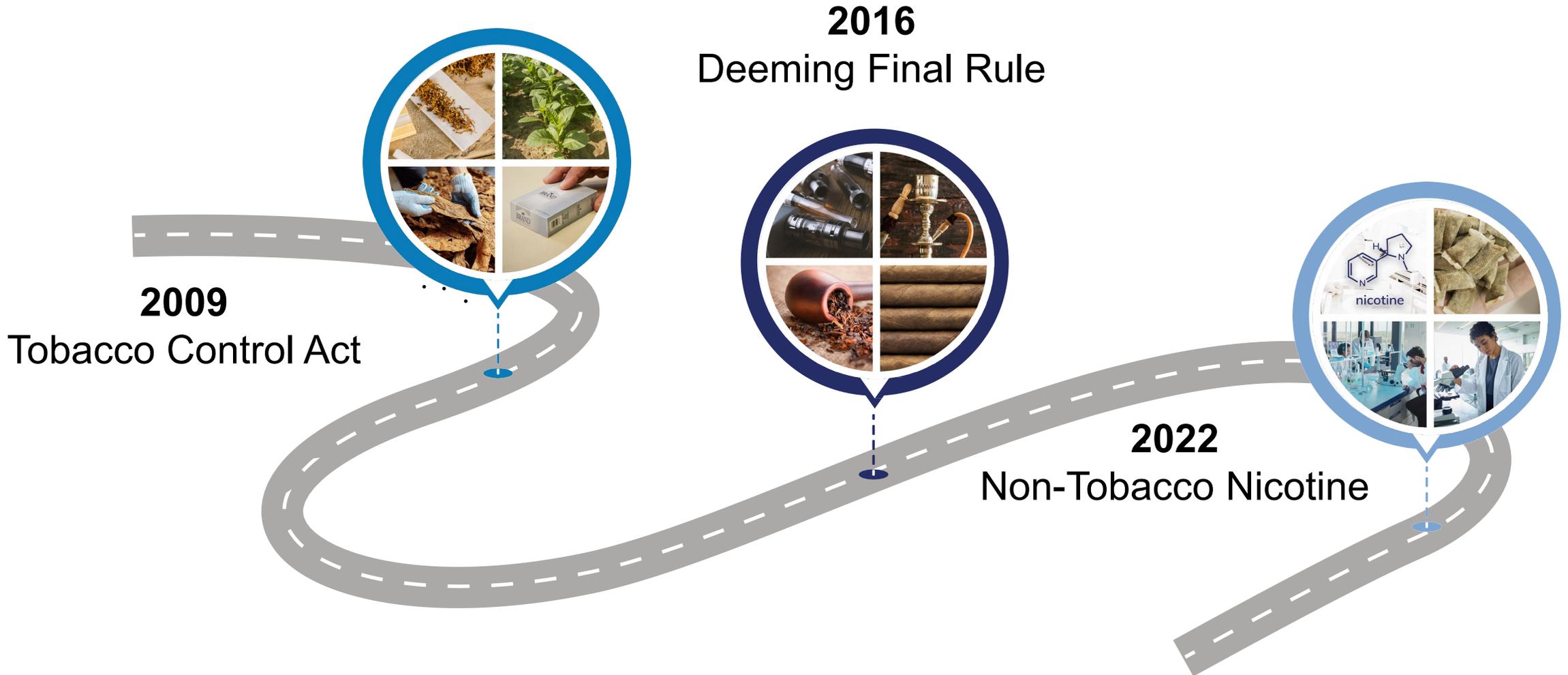
*Brian King, PhD, MPH  
Director, FDA Center for Tobacco Products*

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

The FDA logo is located in the top right corner of the image. It consists of the letters "FDA" in a bold, blue, sans-serif font, set against a white square background.

- **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





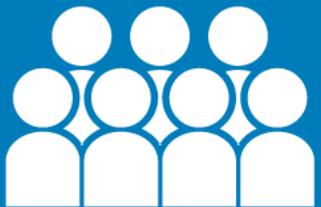
## Review tobacco product applications

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**

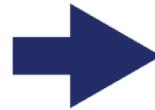


# CTP RESEARCH PROGRAM



**Over 600**

CTP-funded research projects  
from FY10 - FY22

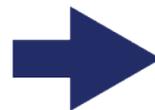


**More than 60%**

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





**PATH**

Population Assessment  
of Tobacco and Health

*A collaboration between the NIH and FDA*

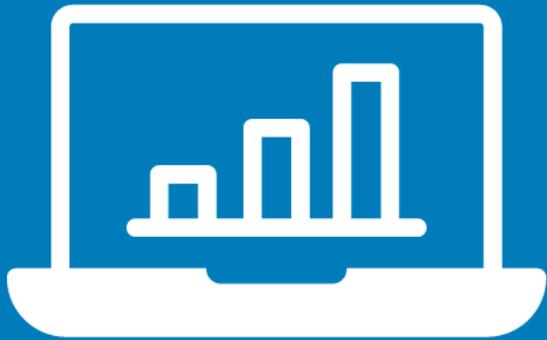
**NYTS**

National Youth

**T O B A C C O**

— 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

# PROGRAMMATIC AREAS



Premarket Review

Product Standards

Compliance & Enforcement

Public Health Education & Resources

A blurred background image of a crowd of people, possibly at a public event or seminar, with a blue color overlay.

## Premarket Review

A blurred background image of a hand holding a pen and writing on a document, with a light gray color overlay.

## Product Standards

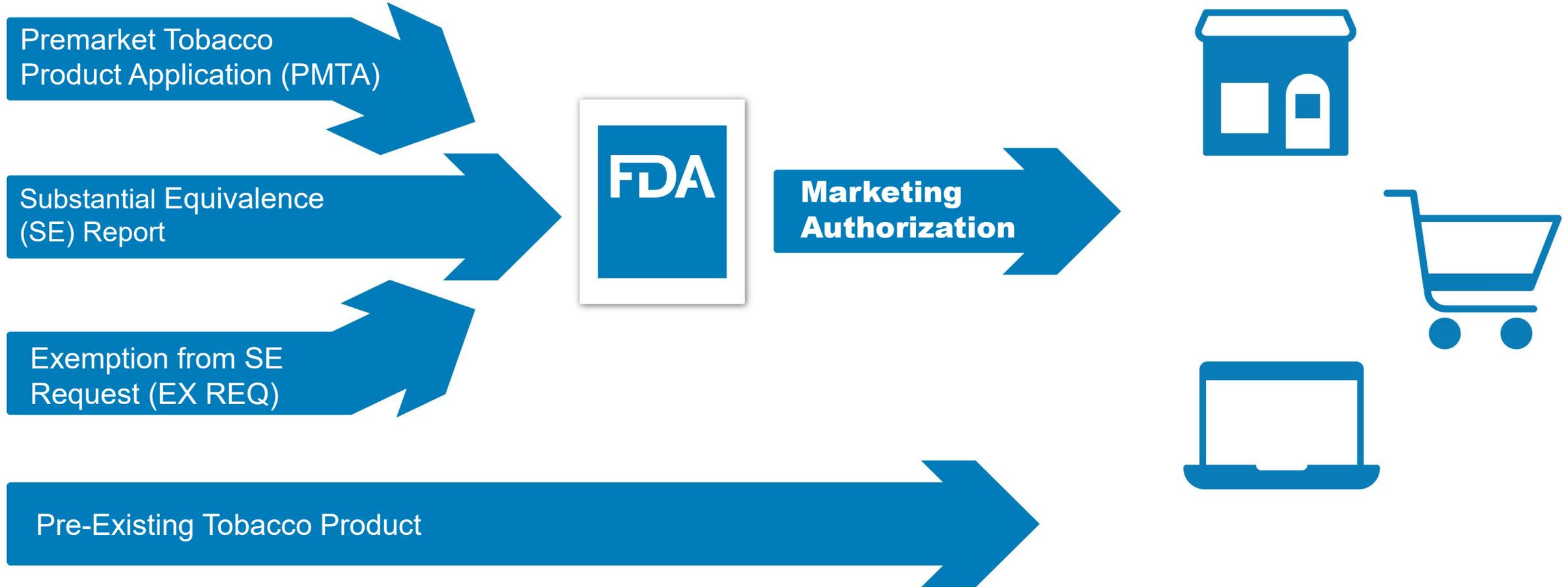
A blurred background image of a woman looking at a book in a library or bookstore, with a light gray color overlay.

## Compliance & Enforcement

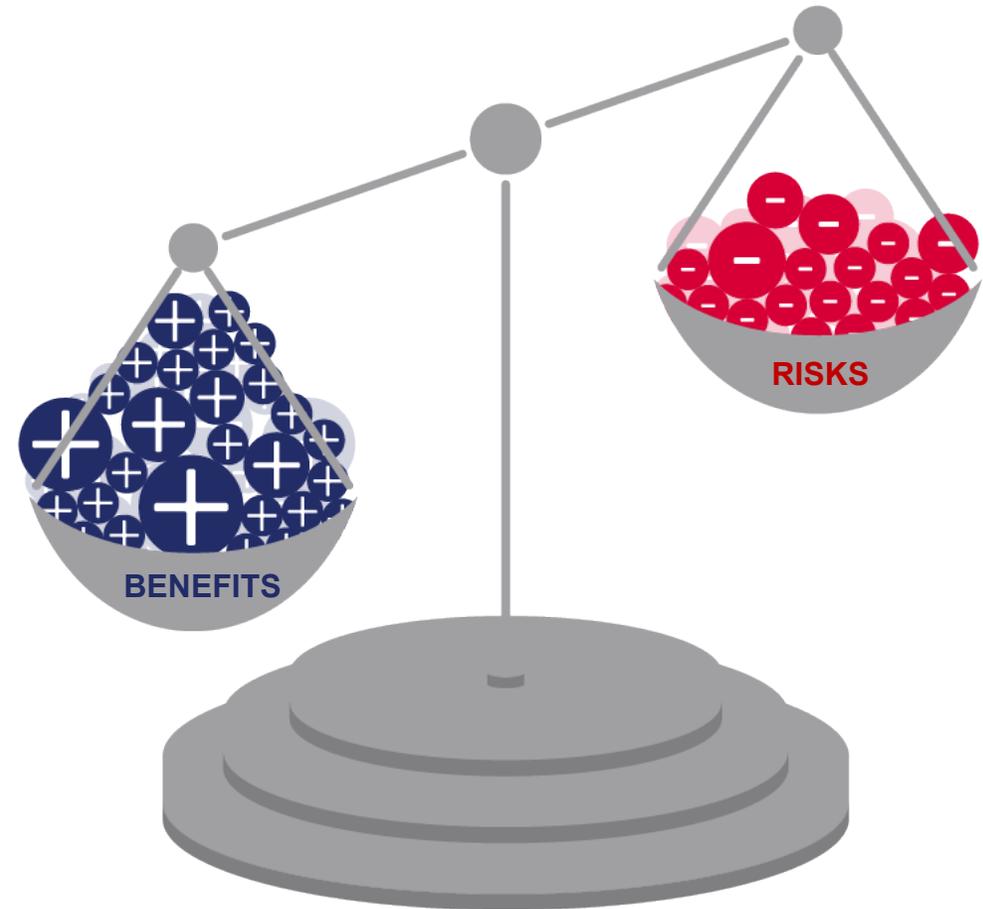
A blurred background image of a woman smiling, with a light gray color overlay.

## Public Health Education & Resources

# PATHWAYS TO MARKET



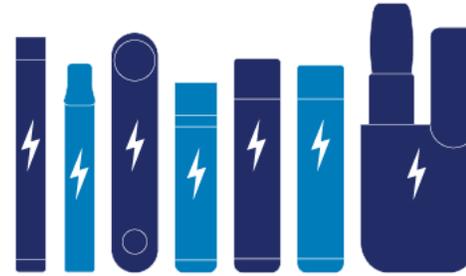
**“Appropriate for  
the Protection of  
the Public Health”**



# APPLICATION REVIEW STATUS TOTAL: PMTA FY20-23



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

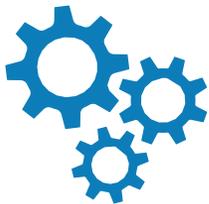


INDIVIDUAL  
HEALTH IMPACT

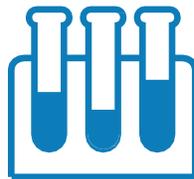


POPULATION  
HEALTH IMPACT

ENGINEERING



CHEMISTRY



TOXICOLOGY



BEHAVIORAL AND  
CLINICAL  
PHARMACOLOGY



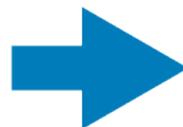
MICROBIOLOGY



# 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)*

# PROGRAMMATIC UPDATES



Premarket Review

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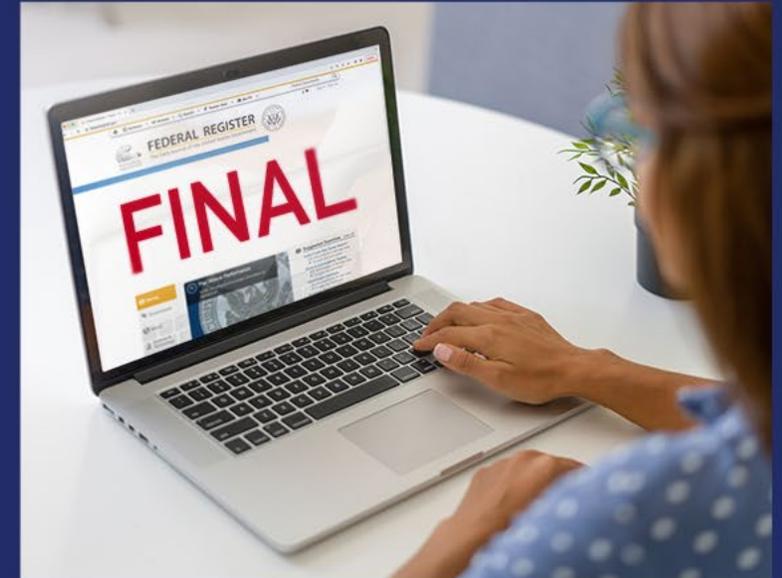
# RULEMAKING PROCESS



Rule/Regulation Proposed

Public Comments Considered

Final Rule Issued



# PROPOSED MENTHOL & FLAVORED CIGAR PRODUCT STANDARDS (APRIL 2022)

FDA has **proposed product standards** to:

- Prohibit **menthol** as a characterizing flavor in cigarettes
- Prohibit all **characterizing flavors**, except tobacco, in cigars



- **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

# SCIENTIFIC ASSESSMENTS ON ROLE OF MENTHOL IN CIGARETTES AND FLAVORS IN CIGARS

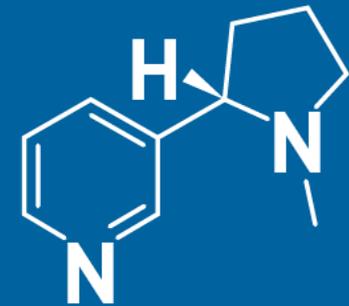


Three scientific assessments were developed and went through FDA's external peer review process



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

NICOTINE



# PROGRAMMATIC UPDATES



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# CTP COMPLIANCE AND ENFORCEMENT ACTIVITIES



**Compliance, Training,  
Education, and Outreach**



**Surveillance, Inspections,  
and Investigations**



**Enforcement Actions**

**Industry Compliance**

# ENFORCEMENT SCOPE



**Manufacturer**



**Importer**

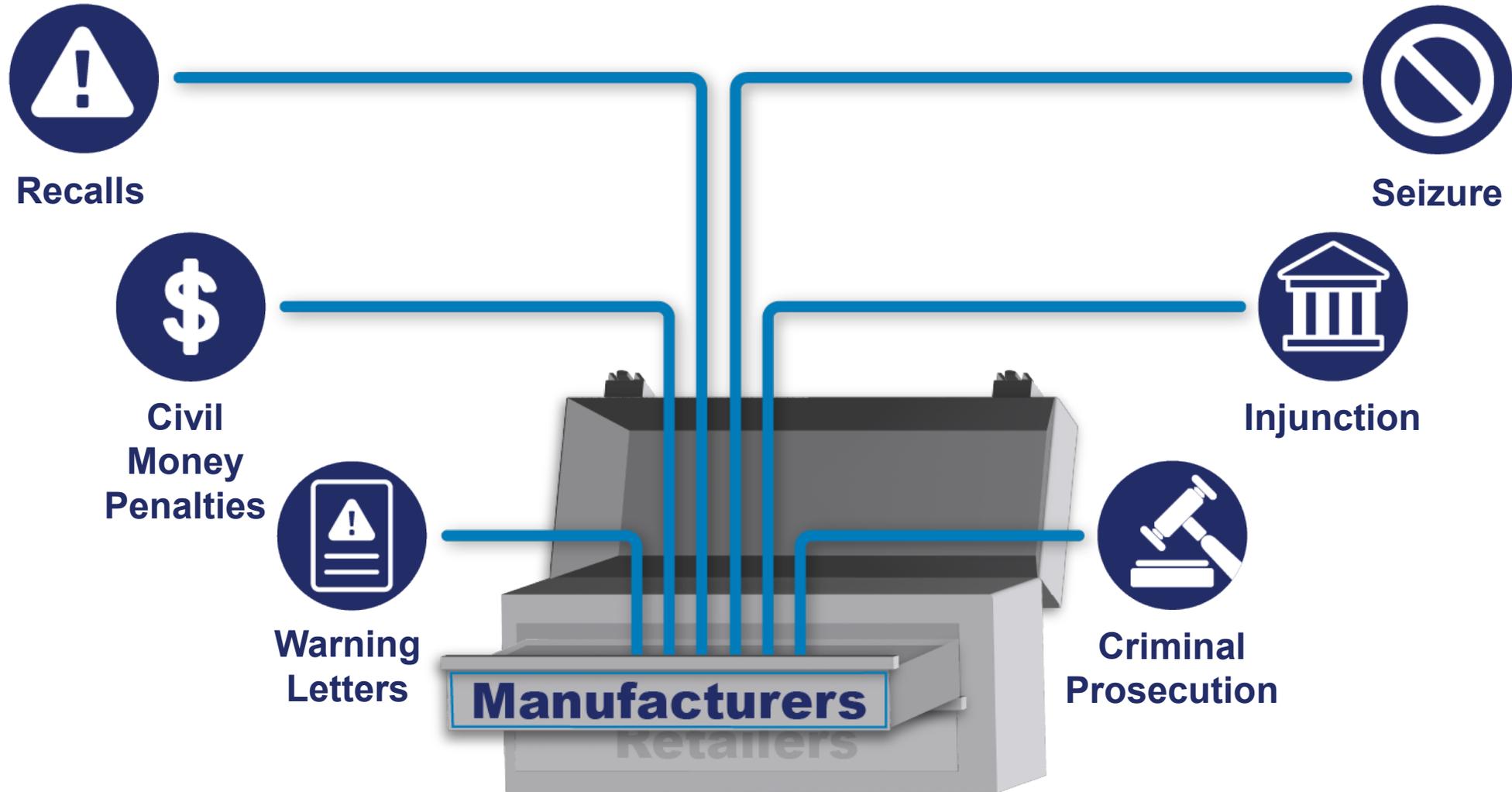


**Distributor**

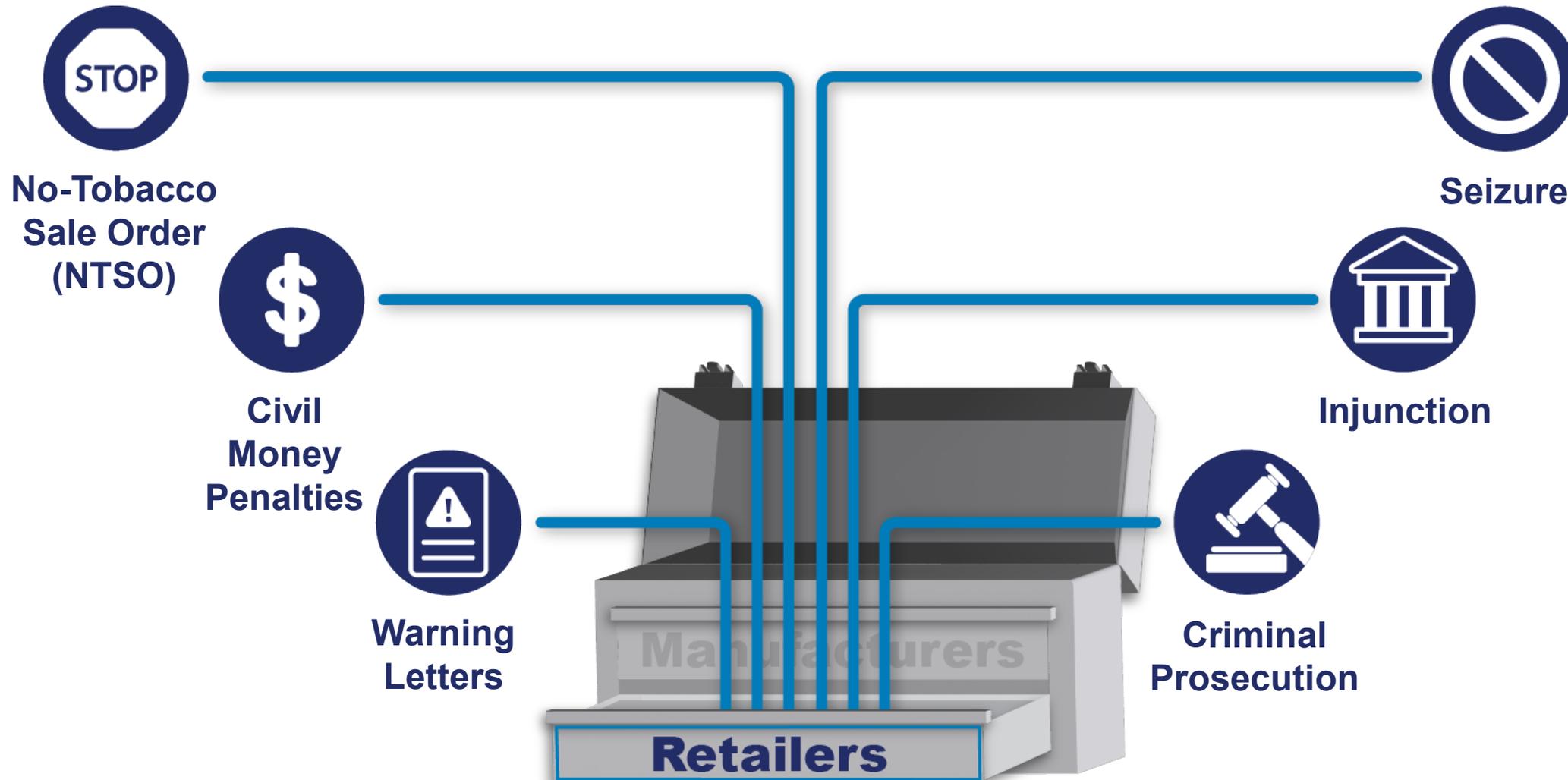


**Retailer**

# COMPLIANCE & ENFORCEMENT: MANUFACTURERS



# COMPLIANCE & ENFORCEMENT: RETAILERS



# ENFORCEMENT ACTIONS



**Online  
Investigations**

Through May 2023,

## >1,200 Warning Letters

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



**Manufacturer**

**~800 WARNING LETTERS  
(OVER 750 FOR ENDS)**

**10 CIVIL MONEY PENALTIES  
(ALL ENDS)**

**6 INJUNCTIONS  
(ALL ENDS)**



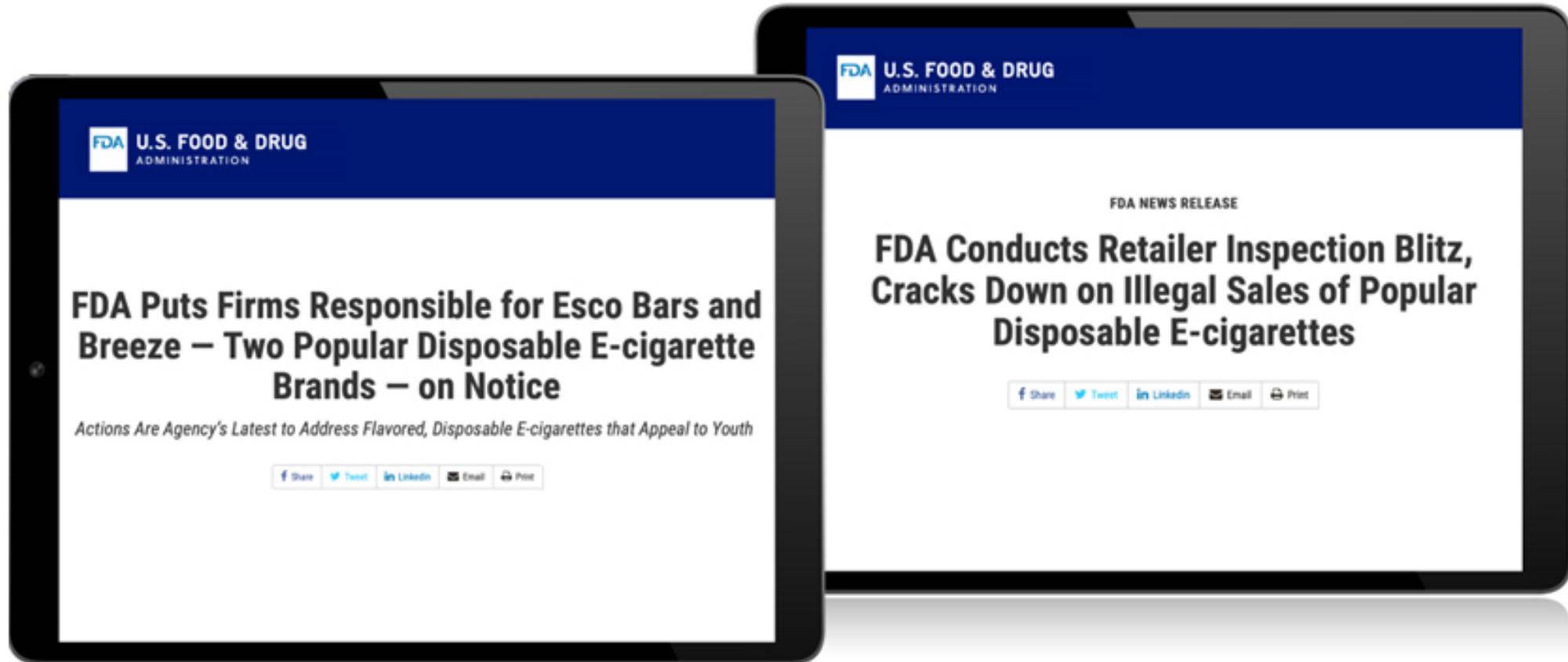
**Retailers**

**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





29,466 Inspection Results Returned 100 Displaying

Basic View Expanded View

Retailer Name	Street Address	City	State	Zip	Sale to UP	Product Type	Decision Date ↓	Inspection Outcome
7-ELEVEN 32801C	1690 SOUTHEAST WALTON ROAD	PORT SAINT LUCIE	FL	34952	Yes	ENDS / E-liquid	05/31/2023	<a href="#">Civil Money Penalty</a>
7-ELEVEN 40321A / SUNOCO	420 MAGNOLIA AVENUE	AUBURNDALE	FL	33823	Yes	Cigar(s)	05/31/2023	<a href="#">Civil Money Penalty</a>
BROKEN GLASS SMOKE SHOP	343 SOUTHEAST PORT SAINT LUCIE BOULEVARD	PORT SAINT LUCIE	FL	34984	Yes	ENDS / E-liquid	05/31/2023	<a href="#">Civil Money Penalty</a>
CHAMPS 98	804 SOUTH MAIN STREET	AUXVASSE	MO	65231	Yes	Cigar(s)	05/31/2023	<a href="#">Civil Money Penalty</a>
CONOCO / AREA 71	5439 STATE HIGHWAY 165	BRANSON	MO	65616	Yes	Smokeless tobacco	05/31/2023	<a href="#">Civil Money Penalty</a>
FAST LANE / PHILLIPS 66	2301 SOUTH OLD HIGHWAY 94	SAINT CHARLES	MO	63303	Yes	Cigar(s)	05/31/2023	<a href="#">Civil Money Penalty</a>
FOOD MAX	5730 10TH AVENUE NORTH	GREENACRES	FL	33463	Yes	Cigar(s)	05/31/2023	<a href="#">Civil Money Penalty</a>
JUSTIN'S DELI MARKET	304 GRAND AVENUE	NEW HAVEN	CT	06513	Yes	Cigar(s)	05/31/2023	<a href="#">Civil Money Penalty</a>
KROGER FUEL CENTER	1028 SOUTH MONROE							

# PROGRAMMATIC UPDATES



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# TOBACCO PREVENTION CAMPAIGNS



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





- 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**

- 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





## 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



**FDA CTP Research**



**NIH Tobacco Regulatory  
Science Program**



**Federal Business  
Opportunities Website**

# QUESTIONS?



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**AskCTP@fda.hhs.gov**



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**Additional platforms  
to interact with FDA**



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