CENTER FOR RAPID SURVEILLANCE OF TOBACCO (CRST)

FDA CENTER FOR TOBACCO PRODUCTS

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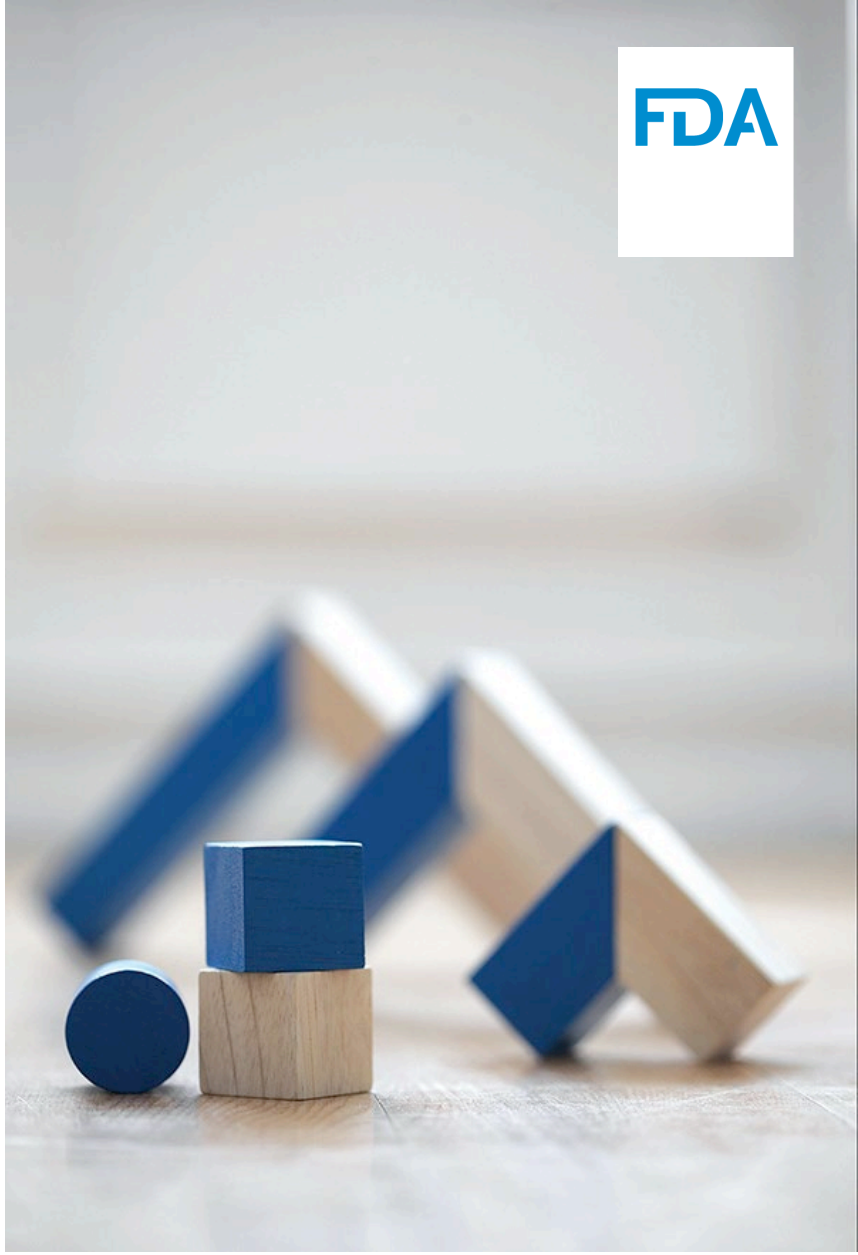

FDA'S TOBACCO PRODUCTS REGULATORY SCOPE

- Since June 2009, CTP has had authority to regulate tobacco products intended for human consumption to reduce harm across the population
  - Immediate authority to regulate the manufacture, marketing, and distribution of **cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco**
- Effective August 2016, an FDA rule "deemed" **all products meeting the statutory definition of tobacco product**, including components or parts (but excluding accessories), to be subject to FDA's tobacco product authorities, including:
  - ENDS (e-cigarettes, e-cigars, vape pens, etc.)
  - All cigars
  - Pipe tobacco
  - Nicotine gels
  - Waterpipe (hookah)
  - Dissolvables not already under the FDA's authority
  - Future tobacco products

THE TOBACCO CONTROL ACT'S AUTHORITIES

- The Tobacco Control Act amended the Food, Drug, and Cosmetic Act to provide FDA authority for:
  - Premarket review of new and modified risk tobacco products
  - Post-market surveillance
  - Product standards
  - Reporting of ingredients
  - Reporting of harmful and potentially harmful constituents
  - Adverse event reporting
  - Health warnings
  - Advertising and promotion restrictions
  - User fees

CTP SUPPORT OF NATIONAL DATA COLLECTION

National Health Interview Survey
Since 1957

nhanes
The Nation's Mobile Health Survey

PRAMS
PREGNANCY RISK ASSESSMENT MONITORING SYSTEM

Tobacco Use Supplement
Current Population Survey

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

FDA'S NEED FOR RAPID SURVEILLANCE

- Tobacco product landscape is rapidly evolving
  - Variety of tobacco products, including characteristics and constituents
  - Dual and poly tobacco among youth and adults
- Rapid increase in use of ENDS by youth
- Shift in age of initiation of smoking from youth into young adulthood
- Persistent tobacco-related disparities
- Variability in policy contexts
- Monitoring tobacco industry marketing
- Post-market surveillance of authorized tobacco products

HOW FDA IS USING ITS TOBACCO AUTHORITIES

- Understand the regulated products
- Review new products before they can be marketed
- Review the claims for proposed modified risk products that state/imply reduced exposure or risk before they can be marketed
- Restrict marketing and distribution to protect public health
- Working to decrease the harms of tobacco products by authorizing products that pose less risk to public health
- Ensure industry compliance with FDA regulation through education, inspections, and enforcement
- Educate the public about FDA's regulatory actions
- Expand the science base for regulatory action and evaluation

PURPOSE OF CRST

Assess changes in use behaviors, product marketing, and the marketplace to better understand the rapidly evolving tobacco landscape in the United States

- Rapid or sentinel data sources or systems can provide:
  - Timely data on changing tobacco use patterns
  - Information about conventional and new authorized products and factors that contribute to their use
  - Observe changes in the tobacco marketplace

CTP AS A SENTINEL SITE

- CTP surveillance data sources
  - Sales data
  - Advertising data
  - Poison control data
  - Adverse event data
  - Social media monitoring
  - Consumer use behaviors and perceptions
  - News and regulation tracking

QUESTIONS?

- Report adverse experiences with tobacco products: https://www.safetyreporting.hhs.gov
- Report Potential Tobacco Product Violation: https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation
- Call us: (877) CTP-1373
- Email us: AskCTP@fda.hhs.gov
- Follow us on Twitter: @FDATOBACCO