TRANSLATING FDA/CTP AUTHORITY INTO REGULATORY ACTION

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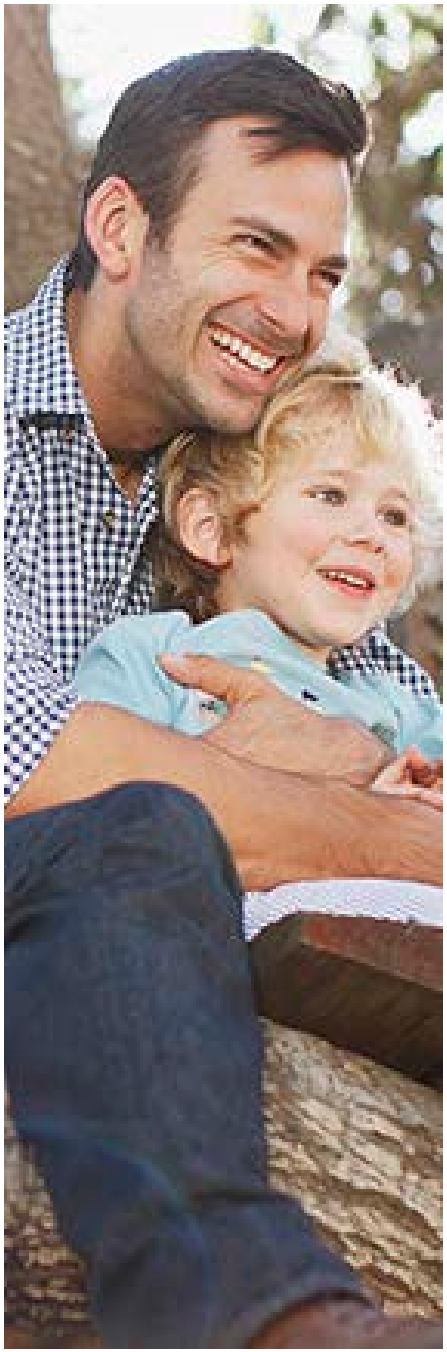

CENTER FOR TOBACCO PRODUCTS

Presented by
Mitch Zeller
Director

November 18, 2014

PRESENTER DISCLOSURE

Mitchell Zeller, JD
Center for Tobacco Products
US Food and Drug Administration

No relationships to disclose

OVERVIEW OF TODAY'S PRESENTATION

- The public health framework
- Building the foundation
- Pursuing strategic priorities

THE PUBLIC HEALTH FRAMEWORK

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FIGHTING AN UPHILL BATTLE AGAINST DISEASE AND DEATH

1900

100 Million Worldwide
PREMATURE DEATHS

2000

1 Billion Worldwide
PREMATURE DEATHS

2100

PREVENTING THE PREVENTABLE IN THE U.S.

- Progress since first SGR – despite huge strides, 42 million adults still smoke
- Still the leading cause of preventable disease and death – nearly 500,000 Americans die each year and 16 million more live with disease
- Every day over 3,200 teens smoke their first cigarette
- More than 700 youth become daily smokers

IMPLEMENTING THE TOBACCO CONTROL ACT

CTP has authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah

ACTING TO IMPROVE PUBLIC HEALTH

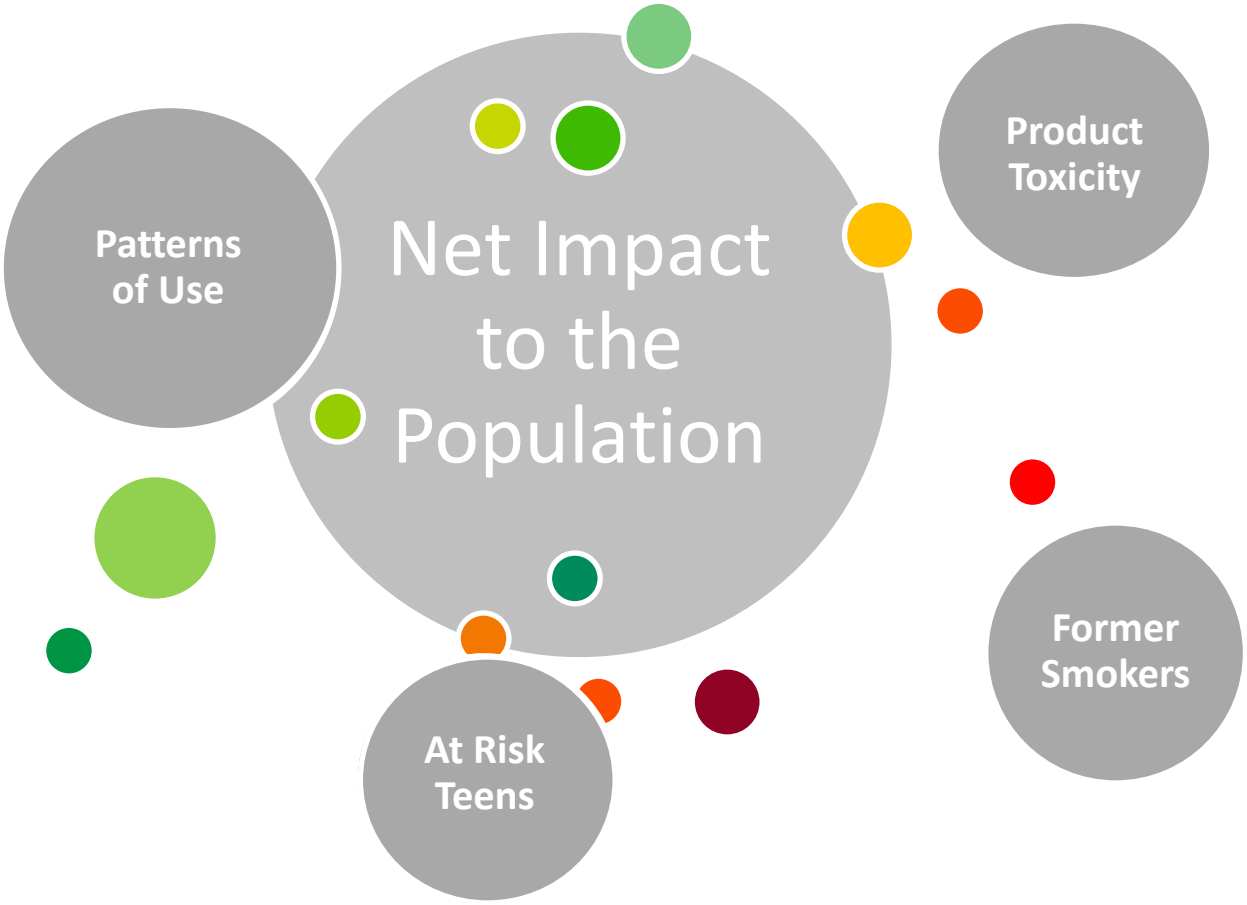
- Prevent youth tobacco initiation
- Encourage adults who use tobacco to quit
- Reduce product harms and addictiveness




DEFINING A PUBLIC HEALTH STANDARD

- Pursue a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard
- Take into account the benefits and the risks of regulatory actions to both users and non-users of tobacco products
- Assess the “net” population-level health impacts of tobacco products

ASSESSING OVERALL IMPACT TO PUBLIC HEALTH



DELVING INTO DEEMING

E-Cigarettes Face First Regulations

Fast-Selling Devices Would Need FDA Approval, Be Banned From Minors; Flavored Ones to Be Allowed

By Thomas M. Burton And Mike Esterl

Vapor Vendors

New U.S. Rules On E-Cigarettes To Be Proposed

Ban Sought on Selling to People Under 18

By SABRINA TAVERNISE

FDA outlines plan to regulate e-cigarettes

By Brady Dennis

The Food and Drug Administration will for the first time regulate the booming market of electronic cigarettes, as well as cigars, pipe tobacco and hookahs, under a proposal to be released Thursday.

The move would begin to place restrictions on e-cigarettes, a nearly $2 billion industry that for years has operated outside the reach of federal regulators. If adopted, the government's plan would force manufacturers to curb sales to minors, stop handing out free samples, place health warning labels on their products and disclose the ingredients. Makers of e-cigarettes also would be banned from making health-related claims without scientific evidence.

The FDA's proposal stops short of broader restrictions sought by many tobacco-control advocates. Regulators at this point are not seeking to halt online sales of e-cigarettes, curb television advertising, or ban the use of flavorings such as watermelon, grape soda and piña colada – all tactics that critics say are aimed at attracting young smokers and that have

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DELVING INTO DEEMING (CONT.)

- On April 24, FDA proposed a new rule that would extend CTP's authority to cover additional tobacco products
- Products that would be "deemed" to be subject to FDA regulation are those that meet the statutory definition of tobacco product, including:
  - Electronic Cigarettes (e-cigarettes)
  - Cigars
  - Pipe Tobacco
  - Nicotine Gels
  - Waterpipe (Hookah)
  - Tobacco Dissolvables not already under the FDA's authority

DEFINING AUTOMATIC PROVISIONS

- Prohibit adulteration and misbranding
- Requirement for ingredient listing
- Requirement for registration and product listing
- Review of Substantial Equivalence (SE) filings and premarket applications (PMTA) for newly deemed products
- Elimination of misleading descriptors and unproven modified risk claims
- Prohibition of free samples

ADDING ADDITIONAL RESTRICTIONS

- Prohibit sale to individuals under the age of 18 years and require age verification
- Prohibit sale using electronic or mechanical devices, e.g., vending machines, with limited exceptions

ADDING A HEALTH WARNING ABOUT ADDICTION

"WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."

- Required to be displayed on covered tobacco packages and in advertisements
- Product package:
  - ✓ 2 principal display panels (PDP);
  - ✓ Warning area shall comprise 30% of each PDP
- Advertisement:
  - ✓ Occupy at least 20% of the area of the ad
- Requirements the same as for smokeless tobacco

BUILDING THE FOUNDATION

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CREATING THE BUILDING BLOCKS

Building CTP to achieve programmatic goals

- Human resources, IT, acquisitions, logistics, budget
- Policy analysis
- External communications

Developing foundational rules and guidance

- “Deeming” proposed rule
- User fees proposed rule
- Investigational products
- Testing/reporting/disclosure

Setting and funding a research agenda

MEETING WHERE REGULATORS LIVE

PURSUING STRATEGIC PRIORITIES

- Product Standards
- Comprehensive FDA Nicotine Regulatory Policy
- Pre- & Post-Market Controls: Regulations & Product Reviews
- Compliance and Enforcement
- Public Education

PRODUCT STANDARDS

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IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

- Advancing a product standard strategy that yields strong standards to improve public health and can withstand legal challenge

- Exploring potential standards for:
  - Addictiveness
  - Toxicity
  - Appeal

COMPREHENSIVE FDA NICOTINE REGULATORY POLICY

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LOOKING AT NICOTINE DIFFERENTLY

- Establish an integrated, FDA-wide policy on nicotine-containing products that is public-health based
- Implications for tobacco, drug, and device regulatory policy

LOOKING AT NICOTINE DIFFERENTLY

- Recognize that there is a continuum of nicotine-containing products
- Understand that people smoke for the nicotine but die from the tar
- Acknowledge public health opportunity

LOOKING AT NICOTINE DIFFERENTLY

- Related actions include:
  - Finalizing Deeming regulation (Review of over 135,000 comments)
  - Developing jurisdiction policy on nicotine-containing products across FDA
  - Working with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
  - Exploring options at CTP for an expedited premarket review policy based on principle of relative toxicity and risk

PRE- & POST-MARKET CONTROLS: REGULATIONS AND PRODUCT REVIEWS

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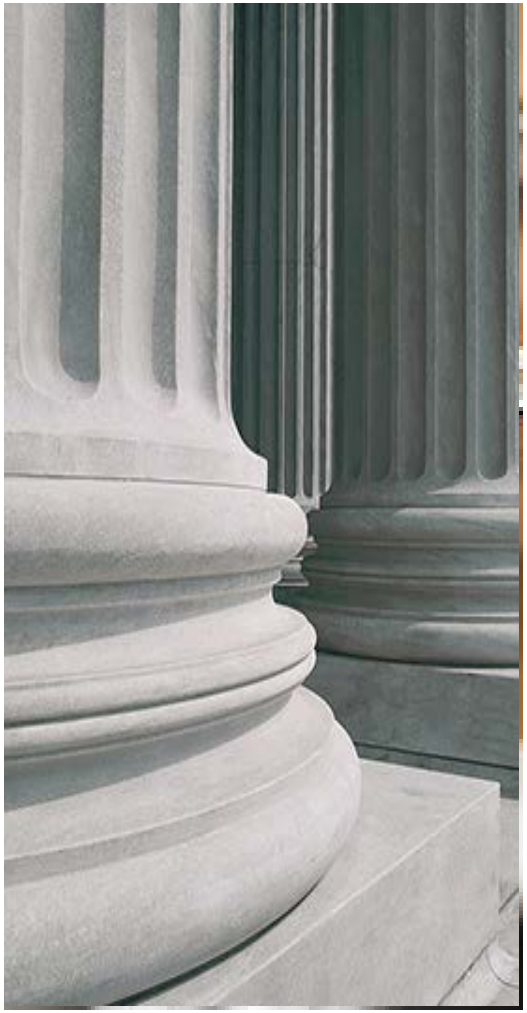
PROTECTING CONSUMERS



As the regulatory gatekeeper, CTP now stands between tobacco products and consumers

SETTING PRE- & POST-MARKET POLICY

- Explore developing rules and guidances for:
  - Product reviews
    - Investigational Tobacco Products (ITP)
    - Premarket Tobacco Application (PMTA)
    - Substantial Equivalence (SE)
    - Exemption from Substantial Equivalence
    - Modified Risk Tobacco Product (MRTP)
  - Tobacco Product Manufacturing Practices (TPMP)
  - Analytic test method validation

MEASURING PROGRESS IN MAKING SE DECISIONS

4,618 SE Submissions

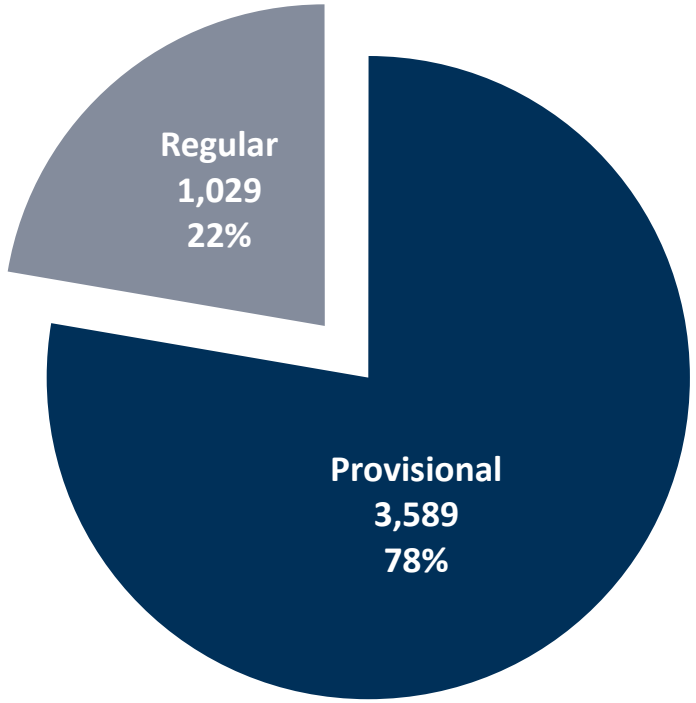
- 99% of acceptance reviews (jurisdiction and administrative) are complete

Regular Reports

- Resolved 45% via Order letter, Refuse-To-Accept letter or Withdrawal
- Review of new regular reports starts upon receipt as there is no backlog
- Established performance measures for review and action

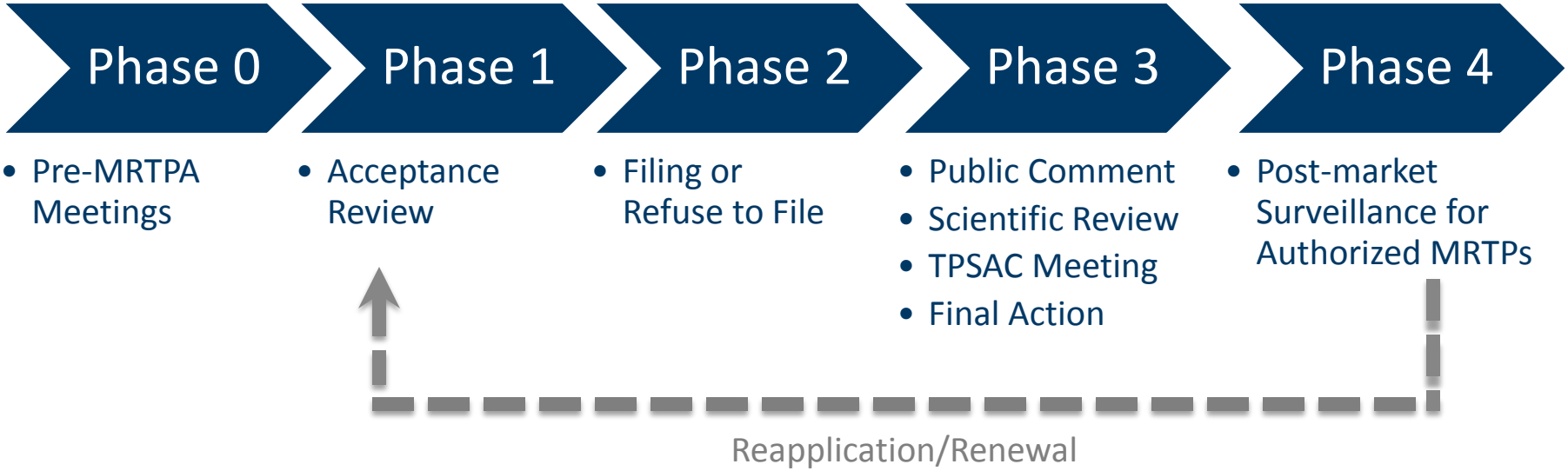
Provisional Reports

- Reviews have begun



Data as of 10/31/14

DEFINING THE MODIFIED RISK TOBACCO PRODUCT PROCESS



REVIEWING MODIFIED RISK TOBACCO PRODUCT APPLICATIONS

- Filed first MRTP applications in August 2014
- Made applications available for comment for 180 days
  - Current comment period closes Monday, February 23, 2015
  - Comments submitted in first 90 days (by Nov. 25) are more likely to be considered before referring applications to Tobacco Products Scientific Advisory Committee
- Published Draft Guidances
  - Draft Guidance for Industry and Staff: Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products
  - Draft Guidance for Industry: Modified Risk Tobacco Products Applications

COMPLIANCE AND ENFORCEMENT

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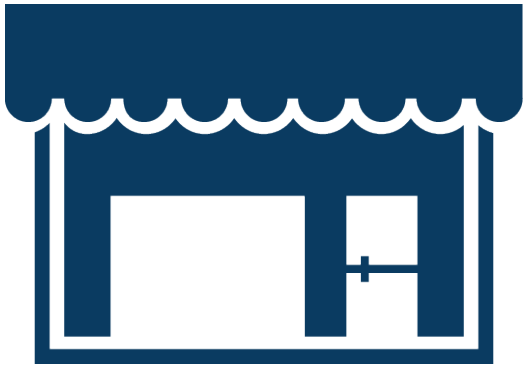
ENFORCING THE LAW

- Inspect, investigate, monitor and review activities
- Initiate appropriate enforcement actions that are supported by evidence
  - Develop and document sufficient evidence to support enforcement actions for violations of the law
  - Expand state inspection program to remaining states and territories
  - Plan for implementation of compliance activities for newly deemed products
  - Implement compliance inspection, education, and enforcement activities on tribal lands

MEASURING COMPLIANCE PROGRESS TO DATE

- Conducted over 356,000 retailer inspections covering 54 states and territories
- Issued more than 20,300 warning letters
- Issued over 2,100 civil money-penalty actions against tobacco retailers
- Awarded FDA's first contracts to Tribal governments to conduct tobacco retail inspections within their jurisdictions



Data through 11/1/14

PUBLIC EDUCATION

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EDUCATING AT-RISK AUDIENCES ON THE DANGERS

10 Million

General "At-Risk" Market
Multicultural
Rural
American Indian/ Alaska Native
LGBT

Prevention

Investing in our Future

New Ad: “The 7,000”

New Ad: “Contract”

MEASURING "THE REAL COST" SUCCESS TO DATE

Paid Media

- Reached more than 96% of our target audience over 20 times each quarter with advertising
- Generated 946 million impressions on youth-focused sites such as MTV.com, IGN.com and Hulu.com

Web and social media

- Engaged 1.8M unique visitors from all 50 states on the website
- Produced 910,325 unique conversations about the campaign via Social Media

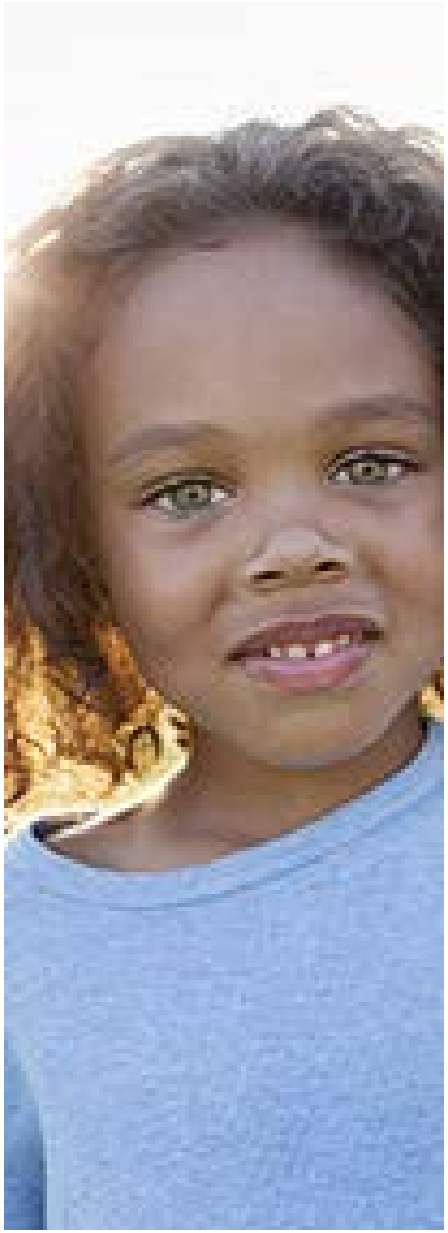
Comprehensive evaluation

- Multi-year, nationwide study consisting of in-person, nationally representative data
- Follow the same youth over 2 years to measure changes in tobacco-related attitudes and behaviors
- Ultimately, results will be used to determine if exposure to the campaign is associated with a decrease in smoking among youth ages 12-17

Data from 2/11/14 – 7/30/14

MAXIMIZING USE OF OUR AUTHORITY FOR A HEALTHIER TOMORROW

- Utilize the tools given to us by Congress to maximize their potential and positively impact public health…by reducing the death and disease caused by tobacco products



THANK YOU

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www.fda.gov/tobaccoproducts