



U.S. FOOD & DRUG
ADMINISTRATION

UPDATES FROM THE FDA CENTER FOR TOBACCO PRODUCTS (CTP)

Mitch Zeller, J.D.
Director, FDA Center for Tobacco Products

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- Update on Regulations and Guidances: Deeming
- Update on Science
- Update on Compliance and Enforcement
- Update on Communication and Public Education



REGULATIONS AND GUIDANCES: DEEMING

FINAL DEEMING REGULATION

- On May 10, 2016, FDA finalized a rule that “deems” 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



Since the start of 2016, FDA issued several deeming-related guidances to assist industry, including:

- PMTA for ENDS Guidance
- Tobacco Product Master Files Guidance
- Investigational Use of Deemed Products Guidance
- Vape Shop Activities Guidance
- Cigar Warning Label Guidance
- Free Sample Guidance

- Generally: The rule was effective on the final rule publication date plus 90 days = **August 8, 2016**
- Applies to “deeming” provision, age restriction, free sample ban, prohibition on vending machine sales, and the requirement for a Modified Risk Tobacco Product Order for any modified risk tobacco products (other than “light,” “low,” or “mild”)

Provisions in the FD&C Act that generally apply to “tobacco products” now automatically apply to deemed products

- Registering manufacturing establishments and providing product listings to FDA
- Reporting ingredients and harmful and potentially harmful constituents to FDA
- Submitting new tobacco products for premarket review and market authorization
- Not selling modified risk tobacco products (including “light,” “low,” or “mild”) unless authorized by FDA

ADDITIONAL PROVISIONS TO PREVENT YOUTH ACCESS



The following restrictions apply:

- No sales to persons under the age of 18 (in person or online)
- Age verification by photo ID required for anyone under 27
- No sale in vending machines where anyone under age 18 has access at any time
- No free samples of deemed tobacco products

- Grandfather date
- Cigars
- Ongoing litigation
- Hunter legislation

A close-up photograph showing a healthcare professional in white gloves using a handheld glucose meter to test a patient's finger. The patient's hand is held steady by another gloved hand. The meter's screen displays the number "277". A blue test strip is inserted into the meter. The background is blurred, showing a clinical setting with blue scrubs.

SCIENCE

NOTEWORTHY SCIENTIFIC ACTIONS: NICOTINE POLICY AND RESEARCH

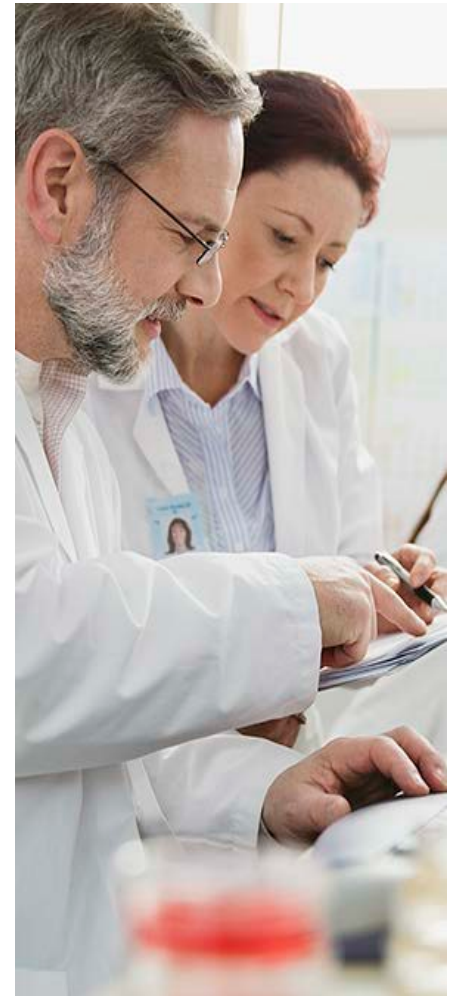
- Developing an integrated, FDA-wide policy on nicotine-containing products that is public health-based
- Increasing our knowledge of tobacco products through focused ground-breaking research
- Tobacco Centers of Regulatory Science (TCORS)
 - Funding opportunity (open June-July 2017) to support biomedical and behavioral research that will provide scientific data to inform regulation of tobacco products
- Population Assessment of Tobacco and Health (PATH) Study
 - Initial data showed that more than a quarter of American adults were current users of tobacco in 2013–14 and roughly 9 percent of youth reported using tobacco in the past 30 days
 - Wave 3 completed, Wave 4 currently in the field



NOTEWORTHY SCIENTIFIC ACTIONS: PRODUCT REVIEW



- New products (those not marketed as of February 15, 2007, or products modified after that date) are subject to premarket review
- Currently reviewing the first applications for newly-regulated products
- First decision on Modified Risk Tobacco Product Applications (MRTPs) issued in December 2016
- Continued reviewing products and issuing marketing decisions:
 - Completed 99% of acceptance reviews for full, regular Substantial Equivalence (SE) submissions
 - Resolved 79% of regular SE reports with decision via refuse-to-accept, withdrawal, substantially equivalent or not substantially equivalent



COMPLIANCE AND ENFORCEMENT

MEASURING COMPLIANCE ACCOMPLISHMENTS

- Conducted over 758,000 retailer inspections covering 56 states and territories
- Issued more than 56,900 warning letters
 - 336 warning letters issued for selling cigarettes, cigarette tobacco, or roll-your-own tobacco that are labeled as flavored
- Initiated 11,800 civil money penalty actions for repeated violations (3,630 in FY16)
- Initiated 43 No Tobacco Sale Orders for violation of certain restrictions, including repeated sales to minors



Data as of 4/1/17

- Vape shop/manufacturing inspections are underway
- Since August 2016, issued over 4,000 Warning Letters to brick and mortar and online retailers for selling e-cigarettes, e-liquids and cigars to minors with flavors like Grape Jolly Rancher, Cookie "Monsta," Bubble Gum, Cotton Candy, and Gummy Bear
- Learn more, including seeing inspection photos, at:

CTP's Compliance and Enforcement Initiatives Post-Deeming

Presented by Ann Simoneau

Director, CTP Office of Compliance & Enforcement

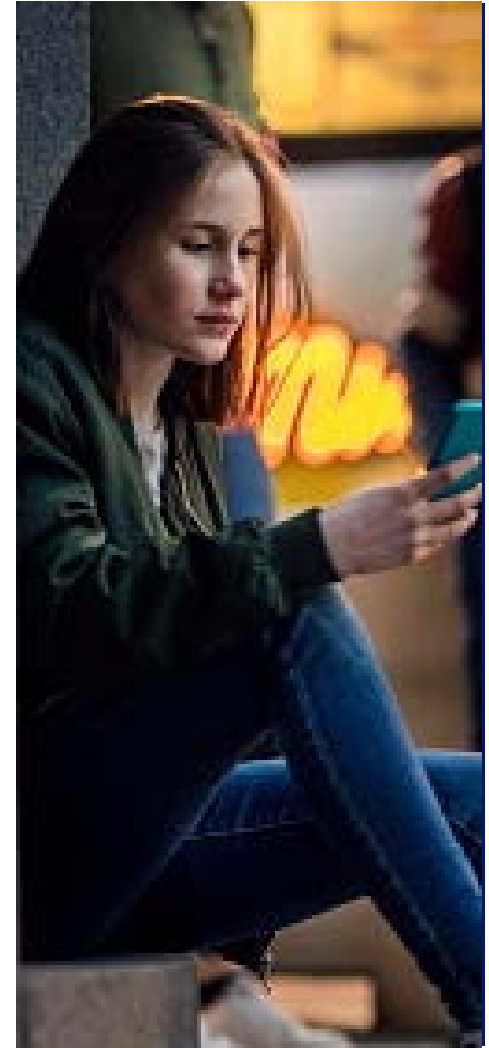
Tomorrow, 11:30 am

A photograph of three young adults (two women and one man) sitting outdoors and talking. The man is in the center, wearing a teal t-shirt. The woman on the left has long blonde hair and is wearing a purple top, holding a stack of books. The woman on the right has curly brown hair and is wearing a white tank top under a dark blue jacket. They are all smiling and looking towards each other. The background shows a light-colored building with several windows.

COMMUNICATION AND PUBLIC EDUCATION

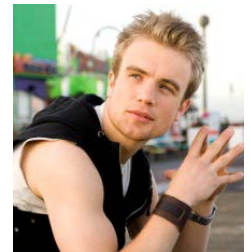
SEEING THE IMPACT OF PUBLIC EDUCATION

- More than **17 million unique web visitors** to campaign websites
- More than **21 million interactions** on campaign social media sites (e.g. likes, shares and comments)



- “The Real Cost,” has **prevented nearly 350,000** youth aged **11 to 18** nationwide from initiating smoking from 2014 to 2016
 - Almost 9 in 10 youth reported seeing “The Real Cost” ads within 7 months of the launch
 - **Positively influenced tobacco-related risk perceptions** and beliefs specific to tobacco after 15 months
 - High levels of exposure to campaign messaging were associated with **a 30 percent decrease** in the risk of **smoking initiation** among youth aged 11 to 18 ¹

¹ 1/20/2017 MMWR



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