THE FDA CENTER FOR TOBACCO PRODUCTS: ITS ROLE IN REDUCING TOBACCO USE

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OVERVIEW OF TODAY’S PRESENTATION

• Update on CTP activities related to our regulatory authorities
• CTP’s strategic priorities
FDA’S REGULATORY AUTHORITIES
FDA is using our regulatory authority to:

• Understand the regulated products
• Restrict product changes to protect public health
• Prohibit modified risk claims that state/imply reduced risk without an order
• Restrict marketing and distribution to protect public health
• Decrease harms of tobacco products
• 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
UNDERSTAND THE REGULATED PRODUCTS

- Companies must register manufacturing facilities and provide a list of all their regulated products.

- The statute requires that FDA make registration and listing data available to the public—see FDA’s Registration and Listing Database: http://www.accessdata.fda.gov/scripts/ctpocerl/index.cfm?action=main.home

- The proposed Deeming Rule requires manufacturers to report on newly deemed products (ex. e-cigarettes, cigars, hookah tobacco) to the FDA.
Restrict product changes that affect public health

Continue to issue regulations and guidances to help regulated industry understand and comply with the premarket review process.
5,574 SE Submissions

• Regular Reports
  • Resolved 68% 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
  • Resolved 15% via Order letter, Refuse-To-Accept letter or withdrawal

• First PMTA marketing orders in November 2015
RESTRICT PRODUCT CHANGES THAT AFFECT PUBLIC HEALTH

• FDA posts on our website the list of products that were once marketed but now cannot be sold

• First provisional NSEs in 2014

• September 2015: FDA issued an order to stop the further sale and distribution of four R J Reynolds products, including Camel Crush Bold, because the submissions did not meet statutory requirements

  - Products can no longer be sold, distributed, imported or marketed in interstate commerce; 30-day period of enforcement discretion for retailers has expired
PROHIBIT FALSE/MISLEADING CLAIMS OF REDUCED RISK

• First ever MRTP application filed August 2014 by Swedish Match and is under review – application and required Tobacco Product Scientific Advisory Committee (TPSAC) meeting are publicly available on the CPT website

• In August, 2015, FDA took action against three tobacco manufacturers for making “additive-free” and/or “natural” claims on cigarette labeling
Prohibit misleading descriptors (light, low, mild).

• FDA takes action when such products are found to be illegally sold or marketed, including on the web

Warning Letters issued to e-cigarette companies illegally making FDA-related claims
RESTRICT MARKETING AND DISTRIBUTION

In the proposed deeming rule, FDA prohibits, for newly deemed products:

- Sales to people younger than 18; proof of age by photo ID for purchase < 27 years of age
- Distribution of free samples
- Sales in vending machines, self-service displays except in adult-only facilities
Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah

- Proposed “deeming” rule to assert such jurisdiction published in 2014
  - More than 135,000 comments received
  - Proposed final rule currently under review by Office of Management and Budget (OMB)
DECREASE PRODUCT HARMs

Issued Jurisdictional Proposed Rule

• Describes circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the FD&C Act

Products standards

• Nicotine Exposure Warning & Child-Resistant Packaging for E-Liquids Advanced Notice of Proposed Rulemaking (ANPRM)
  - Seeking information related to nicotine exposure warnings and child-resistant packaging for liquid nicotine, nicotine-containing e-liquid(s), and other tobacco products
Ensuring Industry Compliance – Retailers

Issued guidances to help retailers understand and comply with requirements

Tobacco retailer inspections to check on compliance with FDA regulations

- FDA contracts cover 56 states and territories (including DC).
- FDA also uses its own officers and employees to conduct inspections to ensure comprehensive coverage of states and territories without contracts.
- Contracts with tribes for inspections on tribal lands.
- Violation reporting form: http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm
ENSURE INDUSTRY COMPLIANCE – RETAILERS

• Conducted over 508,000 retailer inspections covering 56 states and territories
  - 35,700 Warning Letters
  - 5,200 Civil Money Penalties (CMPs) (fines)
  - First No-Tobacco Sales Order Complaints (8 issued in October, 2015)

• Monitor online websites for violation of Federal tobacco promotion and advertising restrictions such as marketing or selling flavored cigarettes, having modified risk claims, or selling to a minor.
  - 322 Warning Letters
2014-present:
http://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/TheRealCostCampaign/ucm384433.htm

- Tooth
- Skin
- Bully
- Contract
- The 7000
2015-present:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465004.htm

- I got this
- Break free

Leverages the peer crowd approach to reach at-risk Multicultural youth (ages 12-17) – specifically African-American, Hispanic, Asian/Pacific-Islander – who identify with the Hip Hop culture and encourage them to live tobacco-free
EDUCATE THE PUBLIC: FRESH EMPIRE LAUNCH PLAN

May 2015
• Campaign pilot launched in four cities in the Southeast (Atlanta, GA; Charlotte, NC; Raleigh-Durham, NC; and Birmingham, AL)

October 2015
• Campaign roll-out
• Intend to have local events in cities with significant number of youth who identify with the Hip Hop culture
Health Warnings in the Proposed Deeming Rule:

• Language required on all covered tobacco products
  • WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical

• Additional health warnings for cigars
  • WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
  • WARNING: Cigar smoking can cause lung cancer and heart disease.
  • WARNING: Cigars are not a safe alternative to cigarettes.
  • WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
EXPAND SCIENCE FOR REGULATORY ACTION & EVALUATION

To expand the scientific foundation for FDA tobacco product regulation

• Research supported through National Institutes of Health, Tobacco Regulatory Science Program
  - Investigator initiated awards
  - Supplements to existing grants or cooperative agreements
  - 14 Tobacco Regulatory Science Centers of Excellence (TCORS) in areas of importance to FDA (awarded in Sept 2013)
  - Nicotine Research Center
  - PATH tobacco longitudinal cohort study

• Survey implementation
• Laboratory analyses
THE NEXT THREE YEARS: PURSUING STRATEGIC PRIORITIES

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