The Deeming Rule Explained: What the Public Health Community Needs to Know

Public Health Law Center Webinar
May 19, 2016 – 1PM Central
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The Deeming Rule Explained: What the Public Health Community Needs to Know

Public Health Law Center Webinar
May 19, 2016
Tobacco Control Legal Consortium

Attorneys supporting tobacco control policy change.
Agenda

• Introduction – Maggie Mahoney

• The Deeming Rule & Its Implementation – Mitch Zeller

• Potential Next Steps for the FDA & Policy Options for States & Localities – Desmond Jenson and Joelle Lester

• Q&A – All panelists
Tobacco Control Before 2009
Tobacco Control Act
The Deeming Rule

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Part III

Department of Health and Human Services
Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143
Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule

A Report of the Surgeon General

U.S. Department of Health and Human Services
Where We Need To Be

State

Federal

Local
FDA’S FINAL DEEMING RULE: UPDATE FROM THE CENTER FOR TOBACCO PRODUCTS

Presented by
Mitch Zeller
Center Director
FDA Center for Tobacco Products

May 19, 2016
OVERVIEW OF TODAY’S PRESENTATION

- Automatic Provisions and Additional Restrictions
- Health Warnings
- Cigars
- Components And Parts
- Premarket Review
- Vape Shops
- Free Samples
- Small-Scale Manufacturers
- Additional Regulatory Documents and Resources
TOBACCO PRODUCTS DEEMED TO BE SUBJECT TO THE FEDERAL FOOD, DRUG, & COSMETIC ACT
Since 2009, CTP had 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
On May 5 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
DEFINING AUTOMATIC PROVISIONS AND APPLICABLE REGULATIONS

Provisions in the FD&C Act that generally apply to “tobacco products” now automatically apply to these newly-regulated products

• Registering manufacturing establishments and providing product listings to FDA
• Reporting ingredients and harmful and potentially harmful constituents
• Requiring premarket review and market authorization of new tobacco products
• Placing health warnings on product packages and advertisements
• Not selling tobacco products that make modified risk tobacco claims (including “light,” “low,” or “mild”) unless authorized by FDA
Additional restrictions are added to prevent underage access

- Not allowing products to be sold to persons under the age of 18 (both in person and online)
- Requiring age verification by photo ID for anyone under 27
- Not allowing the sale in vending machines (unless in adult-only facility)
- Not allowing distribution of free samples
REQUIRING HEALTH WARNINGS

• By May of 2018, health warnings are required to be displayed on cigarette tobacco, roll-your-own tobacco, and all newly-deemed covered tobacco products, including on the:

  – Text warnings on product packages covering 30% of principal display panels

    ▪ For packages that are too small for the warning, it may appear on the outer container or be placed on a tag permanently affixed to the product package

  – For cigars sold individually without packaging, all warnings will be placed on a placard near register

  – Advertisements for the products

    ▪ Warning must appear in the upper portion of the area of the ad and occupy at least 20% of the of the area of the ad
• The addiction warning statement reads:

“**WARNING:** This product contains nicotine. Nicotine is an addictive chemical.”

• The final rule includes a self-certification option for covered tobacco products that do not contain nicotine. For these products, the required statement reads:

“**This product is made from tobacco.**”
There are six warning statements for cigars, and cigar packages and advertisements must bear one of the following in accordance with an FDA-approved warning plan:

1. “WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.”
2. “WARNING: Cigar smoking can cause lung cancer and heart disease.”
3. “WARNING: Cigars are not a safe alternative to cigarettes.”
4. “WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.”
5. “WARNING: Cigar use while pregnant can harm you and your baby.”
   or
   “SURGEON GENERAL’S WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.”
6. “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”
Looking Closer at Key Issues: Premium Cigars

- All cigars, including premium cigars, are deemed under the final rule
- No appropriate public health justification to exclude premium cigars
  - Available evidence does not provide a basis to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion
- All cigars pose serious negative health risks
- Premium cigars are used by youth and young adults
- All cigars contain harmful and potentially harmful constituents, and all cigars contain nicotine, an addictive chemical
• Final rule includes components and parts of newly-regulated tobacco products
• Defines “component or part” as: any software or assembly of materials intended or reasonably expected:
  1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or
  2) to be used with or for the human consumption of a tobacco product.
Component or part excludes anything that is an accessory of a tobacco product
LOOKING CLOSER AT KEY ISSUES: PREMARKET REVIEW OF NEWLY-REGULATED PRODUCTS

• Newly-regulated tobacco products are now subject to premarket review requirements unless they were commercially marketed as of 2/15/2007
• These products are grandfathered and would not need premarket review unless the product has been modified
LOOKING CLOSER AT KEY ISSUES: PREMARKET REVIEW OF NEWLY-REGULATED PRODUCTS

- For newly-regulated products on the market as of the effective date, manufacturers will submit applications under staggered timelines specific to each pathway:

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Time to Submit Application</th>
<th>Time to Continue Selling Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption from SE</td>
<td>12 months</td>
<td>+12 months = 24 months</td>
</tr>
<tr>
<td>SE</td>
<td>18 months</td>
<td>+12 months = 30 months</td>
</tr>
<tr>
<td>PMTA</td>
<td>24 months</td>
<td>+12 months = 36 months</td>
</tr>
</tbody>
</table>
LOOKING CLOSER AT KEY ISSUES: PREMARKET REVIEW OF NEWLY-REGULATED PRODUCTS

• Unless FDA issues an order denying or refusing to accept the submissions, manufacturers who meet these deadlines will continue to be able to sell their products during the continued compliance period

• The product will face enforcement unless it has a marketing order in place at the end of the continued compliance period
Establishments that mix and/or prepare combinations of e-liquids or create or modify aerosolizing apparatus for direct sale to consumers for use in ENDS are tobacco product manufacturers.

The combinations vape shops mix and/or prepare and the new or modified aerosolizing apparatuses are new tobacco products.

Vape shops that are manufacturers are subject to all of the statutory and regulatory requirements that apply to manufacturers, including the requirements to register their establishments, list their products, and obtain premarket authorization.
Distribution of free samples of newly-regulated tobacco products is prohibited.

Prospective adult buyers may smell or handle one of the newly-regulated products as long as:

- the free product is not actually consumed, in whole or in part, in the retail facility and
- the prospective buyer does not leave the facility with a free tobacco product.
**LOOKING CLOSER AT KEY ISSUES: SMALL-SCALE TOBACCO MANUFACTURERS**

- Targeted relief for small-scale tobacco product manufacturers
- Small-scale = Manufacturer of any regulated tobacco product employing 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less
  - One-time allowance of an additional six months for initial ingredient reporting
  - One-time allowance of an additional six months for submission of health information
  - For the first 30 months following effective date, FDA intends to grant extensions to small-scale tobacco product manufacturers for SE reports that need additional time to respond to SE deficiency letters
• Generally: The rule is effective on the final rule publication date plus 90 days = **August 8**
• Applies to “deeming” provision and associated automatic provisions, age restriction, free sample ban, and prohibition on vending machine sales
• Compliance periods, during which FDA does not intend to initiate enforcement action for certain automatic provisions to give firms additional time to comply, are included in preamble
ADDITIONAL REGULATORY DOCUMENTS PUBLISHED

- PMTA Draft Guidance for Electronic Nicotine Delivery Systems (ENDS)
- Tobacco Product Master File (TPMF) Guidance
- User Fee Final Rule
  - Small Entity Compliance Guide for User Fees
- Small Entity Compliance Guide for Deeming
• Deeming Landing Page with links to all relevant documents and webpages, including:
  – Office of Small Business Assistance
  – Retailer Information and Materials
• Upcoming webinar series to help industry comply with regulations – topics include:
  – The Final “Deeming Rule” – All Tobacco Products Subject to the FD&C
  – New Regulatory Requirements for Tobacco Retailers
  – New Regulatory Requirement for Vape Shops
  – Retail Compliance Check Inspections: An Overview for TobaccoRetailers
  – New Regulatory Requirements for Tobacco Manufacturers and Importers
  – Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems

AVAILABLE RESOURCES AT FDA.GOV/TOBACCO
THANK YOU

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Our Priorities for FDA Action

Now that the FDA has published the final deeming rule, what are the public health community’s priorities for the agency’s next steps?
Our Priorities for FDA Action

- Flavored Tobacco Products
Our Priorities for FDA Action

- Flavored Tobacco Products
- Advertising and Marketing
Our Priorities for FDA Action

- Flavored Tobacco Products
- Advertising and Marketing
- Internet Sales
Our Priorities for FDA Action

• Flavored Tobacco Products
• Advertising and Marketing
• Internet Sales
• Self-Service Access
Our Priorities for FDA Action

- Flavored Tobacco Products
- Advertising and Marketing
- Internet Sales
- Self-Service Access
- Child-Resistant Packaging
Our Priorities for FDA Action

- Flavored Tobacco Products
- Advertising and Marketing
- Internet Sales
- Self-Service Access
- Child-Resistant Packaging
- Premarket Review
Our Priorities for FDA Action

• Flavored Tobacco Products
• Advertising and Marketing
• Internet Sales
• Self-Service Access
• Child-Resistant Packaging
• Premarket Review
• Enforcement
State and Local Opportunities
Key policy options to protect health

• Prohibiting smoking and tobacco use in public spaces
• Raising taxes on tobacco products
• Establishing minimum pack sizes and minimum prices
• Prohibiting the sale of tobacco products by certain retailers
Key policy options to protect health

• Raising the minimum legal sales age to 21
• Reducing the number of tobacco retailers in a community
• Restricting the location of tobacco retailers
• Prohibiting the sale of classes of tobacco products
Contact Us

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