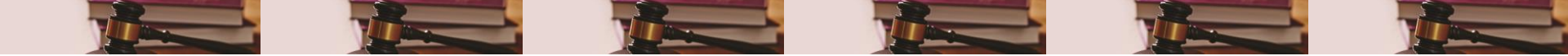

Compliance Central with FDA Center Compliance Directors: Part II

Eric M. Nelson, Director, Division of Compliance, Center for Veterinary Medicine, FDA
Michael W. Roosevelt, Deputy Director, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA
Michael C. Rogers, Assistant Commissioner for Human and Animal Food Operations, Office of Regulatory Affairs, FDA
Ann L. Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, FDA
Moderated by **John R. Manthei**, Partner, Latham & Watkins LLP

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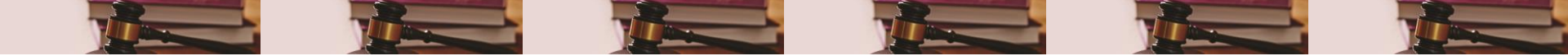

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Compliance Central with FDA Center Compliance Directors: Part II

Michael C. Rogers, MS
Assistant Commissioner for Human and Animal Food Operations
FDA/ORA/OHAFO

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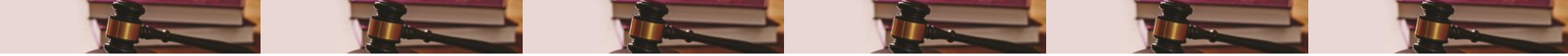

Office of Human and Animal Food Operations (OHAFO)

- About OHAFO
- Program Priorities
  - Produce Inspections
  - Integrated Food Safety System
    - Mutual Reliance Activities
  - Strategic Work Planning
  - Hiring
  - Enforcement Tools & New Approaches

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FDLI'S ENFORCEMENT, LITIGATION, AND COMPLIANCE CONFERENCE

CENTER FOR TOBACCO PRODUCTS

OFFICE OF COMPLIANCE AND ENFORCEMENT

2018 UPDATE

Ann Simoneau, Director
Office of Compliance and Enforcement
Center for Tobacco Products

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

2018 GUIDANCES

Submission of Warning Plans for Cigars (Revised)	Guidance	08/09/2018
Tobacco Retailer Training Programs (Revised)	Guidance	08/09/2018
Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco	Guidance	08/09/2018
Compliance Policy for Required Warning Statements on Small-Packaged Cigars (Revised)	Guidance	08/09/2018
FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)	Guidance	11/06/2018
Listing of Ingredients in Tobacco Products (Revised)	Guidance	11/06/2018
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)	Guidance	11/06/2018

2018 ANPRMs

Tobacco Product Standard for Nicotine Level of Combusted Cigarettes Comment period closed 7/16/2018	ANPRM	3/16/2018
Regulation of Flavors in Tobacco Products Comment period closed 7/19/2018	ANPRM	3/21/2018
Regulation of Premium Cigars Comment period closed 7/25/2018	ANPRM	3/26/2018

DEEMING REGULATION: NEW REGULATORY REQUIREMENTS FOR 2018

Required Warning Statements (as of 8/10/2018)

- Product packages and advertisements must contain warning statements and the warning must follow size and format requirements.
- One addictiveness warning statement on cigarette tobacco, RYO tobacco and "covered tobacco products" packages and advertisements.
- Six rotational cigar warning statements on cigar packages and ads.

"At this time, FDA does not intend to enforce the health warning requirements for cigar and pipe tobacco products. The United States District Court for the District of Columbia issued an order on July 5, 2018 enjoining FDA from enforcing the health warnings requirements for cigars and pipe tobacco set forth in 21 C.F.R §§ 1143.3 and 1143.5 until 60 days after final disposition of the plaintiffs' appeal of the court's order on the health warnings requirements."

DEEMING REGULATION: NEW REGULATORY REQUIREMENTS FOR 2018

Additional Label Requirements (as of 8/10/2018)

Labels for deemed tobacco products must contain:

- The name and place of business.
- Quantity of the contents.
- The statement: “Sale only allowed in the United States” on labels, packaging, and shipping containers of tobacco products.
- Percentage of domestic and foreign-growth tobacco.

Note: FDA indicated, through draft guidance, that it intends to use enforcement discretion regarding section 903(a)(2)(C) of the FD&C Act regarding products that are made or derived from tobacco.

DEEMING REGULATION: NEW REGULATORY REQUIREMENTS FOR 2018

Ingredient Listing Requirement

- Limited to deemed finished tobacco products at this time.
  - Guidance for Industry – Listing of Ingredients in Tobacco Products (April 2018).
- For products on the market as of 8/8/2016, ingredient listing was required to be submitted by 5/8/2018. Small-scale tobacco product manufacturers were required to submit their ingredient listing by 11/8/2018.

  On 11/8/2018, FDA issued a guidance extending the compliance deadline for small-scale manufacturers located in recent FEMA designated major disaster areas for an additional six months.
- For products entering the market after 8/8/2016, ingredient listing must be submitted 90 days prior to marketing.

2018 COMPLIANCE TRAINING AND EDUCATION WEBINARS

- FDA hosted 10 compliance training webinars on federal tobacco regulations.
- These are designed to provide compliance education and information to small businesses and to help tobacco retailers, importers, and manufacturers better understand the agency's regulatory requirements.

Retailer Requirements: New Warning Statement Requirements for Certain Tobacco Products

Tips for Retailers – Preventing Sales to Minors

Importing Tobacco Products

Tobacco Product Listing Updates

Standalone Grandfathered Submissions

Examples of Webinars

FY 2018 Results

- Over 146,000 tobacco retailer inspections completed.
- Over 14,000 Warning Letters issued.
- Over 3,500 Civil Money Penalty Complaints issued.
- 48 No-Tobacco-Sale Order Complaints issued.

2018 COMPLIANCE AND ENFORCEMENT ACTIVITIES

- On 4/24/2018, FDA's Youth Tobacco Prevention Plan was announced.
  - Preventing youth access to tobacco products.
  - Curbing marketing of tobacco products aimed at youth.
  - Educating teens about the dangers of using any tobacco product, including e-cigarettes, as well as educating retailers about their key role in protecting youth.
- Letters issued to 5 ENDS manufacturers requesting documents relating to marketing practices and research on marketing, effects of product design, public health impact, and adverse experiences and complaints related to their ENDS products (FD&C Act § 904(b)).

Nationwide Retailer Inspection Blitz for JUUL Products

- During April 2018, FDA conducted retailer inspections where minors attempted to purchase JUUL products.
- A total of 56 Warning Letters and 6 Civil Money Penalty complaints were issued to retailers during the inspection blitz period.

2018 COMPLIANCE AND ENFORCEMENT ACTIVITIES

- In May 2018, FDA issued 13 Warning Letters jointly with the Federal Trade Commission to companies whose ENDS products resembled kid-friendly food products, including juice boxes, candy, and cookies.
- The tobacco products included in the Warning Letters were misbranded because their labeling and/or advertising which imitated kid-friendly foods was false or misleading.
- Children may mistake these products as food and are at greater risk because exposure to the nicotine in e-liquid products, even in relatively small amounts, could result in acute toxicity.
- As of 12/1/2018, over 30 additional Warning Letters issued.

E-LIQUIDS IMITATING FOOD PRODUCTS

E-liquid

Food product

E-liquid

Food product

E-LIQUIDS IMITATING FOOD PRODUCTS

E-liquid

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Food product

E-liquid

Food product

Nationwide Retailer Inspection Blitz for ENDS Products

- During the summer of 2018, FDA conducted tobacco retailer inspections where minors attempted to purchase ENDS products.
- On 9/12/2018, FDA announced the issuance of enforcement actions to retailers who illegally sold ENDS to minors during the blitz.
  - More than 1,100 Warning Letters.
  - Over 130 Civil Money Penalty Complaints.
- This was the largest coordinated tobacco enforcement effort in FDA history.

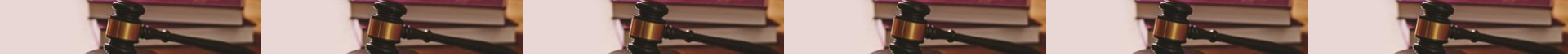
2018 COMPLIANCE AND ENFORCEMENT ACTIVITIES

- On 10/11/2018, CTP and CDER issued a joint Warning Letter to HelloCig Electronic Technology Co. Ltd for selling two e-liquids that contain the prescription drugs tadalafil and/or sildenafil that caused the products to be unapproved new drugs.
- On 10/12/2018, FDA sent letters to 21 ENDS companies seeking information about the marketing status of more than 40 tobacco products.
- On 11/29/2018, FDA sent a Warning Letter to Electric Lotus, LLC for selling tobacco products without required FDA premarket authorization, for selling products that resembled kid-friendly foods, and for failure to comply with the product listing requirements.

2018 NATIONAL YOUTH TOBACCO SURVEY (NYTS) ANNOUNCEMENT

- On 11/15/2018, FDA and CDC released new findings showing that more than 3.6 million middle and high school students were current (past 30-day) ENDS users in 2018.
- Between 2017 and 2018:
  - Current e-cigarette use among high school students increased by 78%.
  - Current e-cigarette use among middle school students increased by 48%.
  - Substantial increase in the portion of youth ENDS users who use their products frequently.
- On 11/15/2018, FDA Commissioner Gottlieb issued a statement proposing new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes.

THE END



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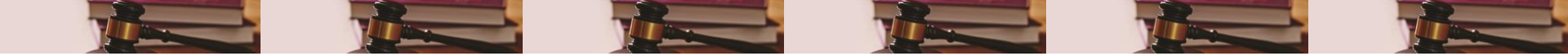

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