FDLI's Enforcement, Litigation, and Compliance Conference

Center for Tobacco Products
Office of Compliance and Enforcement
2017 Update

Ann Simoneau, Director
Office of Compliance and Enforcement
Center for Tobacco Products, FDA
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Guidances Published 2017

Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised*)	Guidance	12/08/16
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Revised*)	Guidance	12/12/16
Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (Revised*)	Guidance	12/15/16
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions (Revised*)	Guidance	12/15/16
Submission of Warning Plans for Cigars	Guidance	12/29/16

Guidances Published 2017

Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops	Draft Guidance	01/13/17
Compliance Policy for Required Warning Statements on Small-Packaged Cigars	Guidance	09/25/17
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised)	Guidance	09/28/17
Prohibition of Distributing Free Samples of Tobacco Products	Guidance	10/11/17
Health Document Submission Requirements for Tobacco Products (Revised)	Guidance	10/18/17
Listing of Ingredients in Tobacco Products (Revised)	Guidance	11/08/17
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)	Guidance	11/08/17

Regulations Published 2017

Refuse to Accept Procedures for Premarket Tobacco Product Submissions	Final Rule	12/29/16
Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"	Final Rule	1/9/17
Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products	Proposed Rule	1/23/17

Final Deeming Regulation: New Deadlines

Cigar Warning Plans

- Cigar warning plans on how warning will be randomly displayed and distributed on packages and rotated on advertisements must be submitted to and approved by FDA.
- **Deadline:** August 10, 2017

Establishment Registration and Tobacco Product Listing

- Entities engaged in the manufacturer, preparation, compounding, or processing of tobacco products in the U.S., prior to August 8, 2016 and continuing operations after August 8, 2016 must register their establishment and submit tobacco product listings.
- Applies to Newly Deemed Finished tobacco products.
- **Deadline:** October 12, 2017

Final Deeming Regulation: New Deadlines

Ingredient Listing

- Each tobacco product manufacturer or importer must submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each regulated tobacco product by brand and by quantity in each brand and subbrand.
- **Deadline:** For products on the market on August 8, 2016: May 8, 2018; or November 8, 2018 for small-scale tobacco product manufacturers.

Tobacco Health Documents

- Each tobacco product manufacturer or importer must submit tobacco health documents that "relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.
- **Deadline:** February 8, 2017 or November 8, 2017 for small-scale tobacco product manufacturers (May 8, 2018 for small-scale tobacco product manufacturers impacted by recent natural disasters).

Final Deeming Regulation
Effective and Compliance Dates

http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm500778.htm

Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deemed Tobacco Products

Quick Facts

- Retailers that mix and prepare e-liquids or create or modify vaporizers will be regulated as both retailers and manufacturers.
- Importers of tobacco products must ensure that the tobacco products they import are in compliance with the law.

The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On May 10, 2016, FDA issued a final rule extending its tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), including electronic nicotine delivery systems (ENDS)—such as e-cigarettes and vape pens—all cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, and certain dissolvables.

On the following chart, we have identified the primary party for complying with the requirements. However, we note that failure to comply with these requirements may render a tobacco product adulterated, misbranded, or both, and it is unlawful for any entity to sell or distribute an adulterated and/or misbranded product in interstate commerce.

Regulations to Prevent Youth Access to Tobacco Products (Found at 21 CFR 1140)

Certain provisions of the deeming regulation only apply to "covered tobacco products."

A "covered tobacco product" is any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to §1100.2, but excludes any component or part that is not made or derived from tobacco. Examples include: e-cigarettes, e-liquid, cigars, hookah (waterpipe) tobacco, pipe tobacco, and dissolvables. Examples of components or parts that are not covered tobacco products include: a pipe or an ENDS atomizer sold without liquid nicotine.

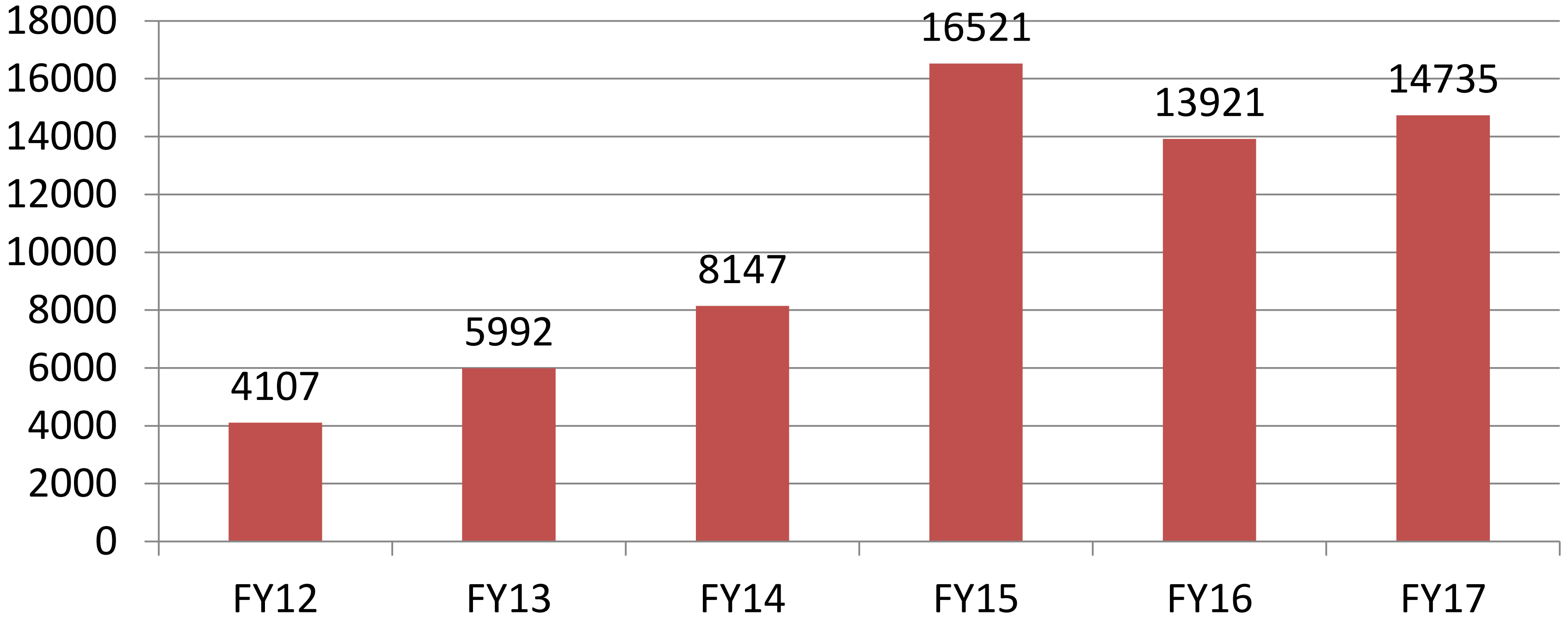
Provision	Newly Deemed Products	Effective Date	Retailers	Manufacturers	Importers	Distributors
Only sell to customers age 18 or older and check photo ID of everyone under age 27	All covered tobacco products	August 8, 2016	X			
Do not give away free samples	All	August 8, 2016	X	X	X	X
Do not sell products in a vending machine Vending machine sales are allowed if in a facility where those under 18 years of age are neither present nor permitted at any time	All covered tobacco products	August 8, 2016	X			

Update: Retailer Compliance Check Inspection Program

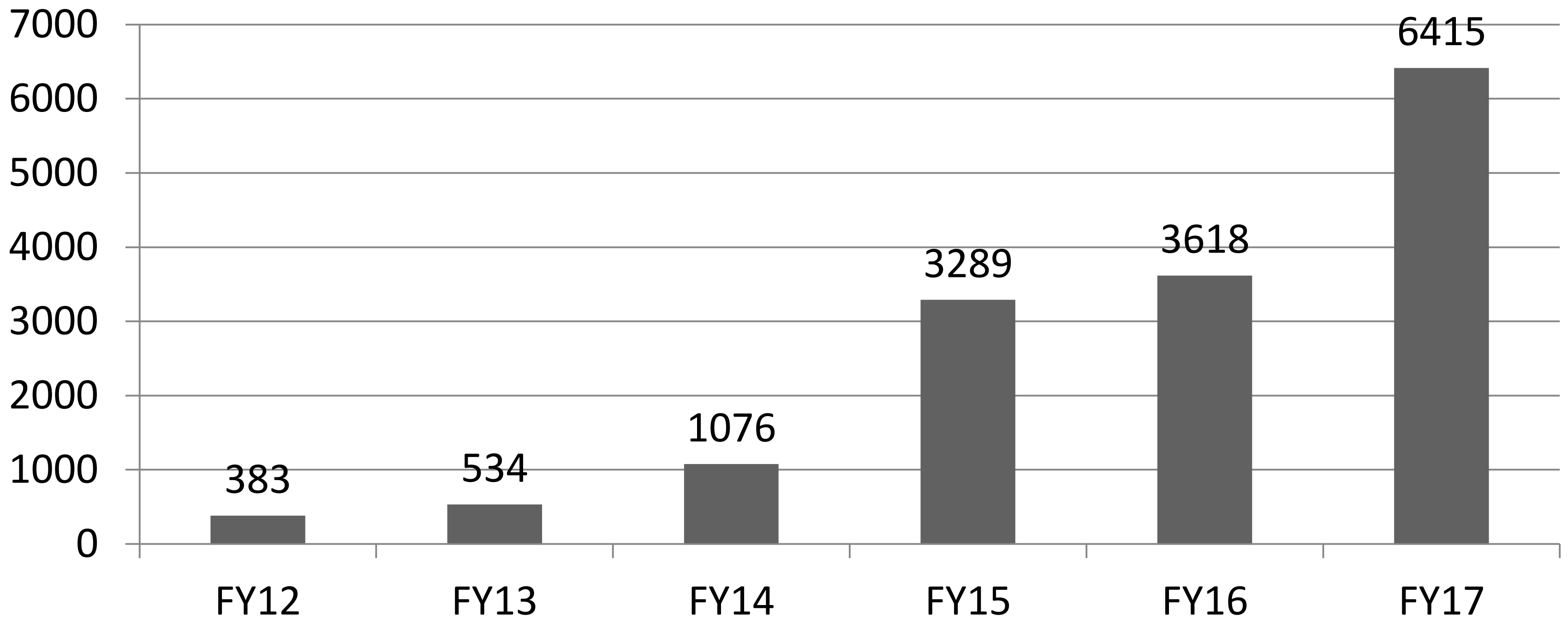
FY17 Results

- Contracts with 57 jurisdictions
  - Includes contracts with 3 Tribes
- FDA uses its own inspectors in areas without contracts
- Over 168,000 inspections completed in FY17

Enforcement: Warning Letters Issued



Enforcement: CMPs Issued



Enforcement: No Tobacco Sale Orders

- More than 55* NTSOs in FY17.
- More than 90* NTSO’s since program began.
- Two retailers had a second NTSO imposed by an ALJ.
- A list of all NTSOs ordered by an ALJ are posted to our website, along with the effective dates of each NTSO.

*** Based on data publicly posted on December 4, 2017**

Internet Surveillance and Enforcement

- FDA conducts routine surveillance of sales, distribution, marketing, and advertising activities related to regulated tobacco products on the websites, online marketplaces, social media platforms and in publications.
- In FY17, FDA issued 140 Warning Letters as the result of surveillance.
- FDA issued more than 500 Warning Letters since the program began.
- These Warning Letters included violations related to:
  - Sale of tobacco products to minors
  - Flavored cigarettes
  - Smokeless tobacco product warning statements
  - FDA approved claims
  - Free samples
  - False or misleading statements

Standalone Grandfather (GF) Determinations

- A grandfathered (GF) tobacco product is a product commercially marketed (other than exclusively in test markets) in the U.S. as of February 15, 2007.
- GF tobacco products are not subject to the premarket requirements of the FD&C Act, but may be used as a predicate product in a 905(j) SE report.
- A firm may voluntarily request a determination of the GF status of their tobacco product. (standalone GF review request)
- Completed more than 1700 standalone GF determinations since program began, more than 300 of which were for newly deemed products.
- FDA maintains a public database with GF determination information. This database does not list all GF tobacco products--only standalone GF determinations. It is updated periodically. (https://www.accessdata.fda.gov/scripts/ctpGnd/)

Vape Shop Inspections

- Conducted Vape Shop Inspections.
- Vape shops can sell a variety of products to consumers including ENDS devices, ENDS replacement pieces, ENDS hardware, ENDS pre-mixed flavored e-liquids, and other ENDS-related products.
- Vape shops can mix or prepare combinations of liquid nicotine, flavors, and/or other liquids for direct sale to consumers for use in ENDS or create or modify aerosolizing apparatus for direct sale to consumers for use in ENDS.
- Depending on the activities a vape shop engages in, it can be a tobacco product retailer, a tobacco product manufacturer, or both. Retailers and manufacturers are subject to inspection by FDA.

FDA Age Calculator

- FDA recently launched a free, voluntary age calculator app.
- “FDA Age Calculator” allows retailers to use a personal smartphone to help determine if a purchaser is old enough to buy tobacco products under federal law.
- Uses camera feature to scan driver’s license (can also be manually entered).
    - Customer’s personal information is NOT transmitted, shared or saved by retailer, third-party or government server.
- Available in iTunes and Google Play.

Compliance Training Webinars

In FY17, FDA provided 7 new compliance training webinars to its website to assist regulated industry.

A Retailer's Guide to 'Covered' Tobacco Products Webinar (15:29)

Using the Tobacco Registration and Listing Module of FURLS - Tips and Recent Enhancements

Required Warning Statements for Cigars (16:35)

This is Our Watch – Tobacco Retailer Education Program

- Developed to educate retailers on how to comply with the law - provides free materials for in-store locations.
- Kit contains: Poster, Flyers, Age-verification Calendar, Register sign, Stickers.
- Printed materials are being mailed directly to over 350,000 tobacco retail locations.
- The materials are also available online for digital download and self-printing.

This is Our Watch –
Tobacco Retailer Education Program

FDA’s Comprehensive Plan for Tobacco and Nicotine Regulation

- On July 28, 2017, FDA Commissioner, Scott Gottlieb, announced a new comprehensive plan that places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts.

Advanced Notice of Proposed Rulemaking (ANPRM)

- Nicotine Product Standard ANPRM
- Flavors in Tobacco Products ANPRM
- Premium Cigars ANPRM

Revised Application Deadlines For Newly Deemed Products

Type	Example	Date
Combustible	Cigars, pipe tobacco, hookah tobacco	Aug. 8, 2021
Non-combustible	E-cigarettes and other ENDS, gels, certain dissolvables	Aug. 8, 2022

- Revised deadlines only for products marketed as of August 8, 2016.
- These applications would be required to meet any product standards issued in interim.
- The revised deadlines will enable manufacturers to submit higher quality, more complete applications (informed by additional FDA rules and guidances).

Additional Foundational Rules and Guidances

- FDA plans to issue foundational rules and guidances including:
  - Premarket Tobacco Application (PMTA) rule
  - Substantial Equivalence (SE) rule
  - Modified Risk Tobacco Product Application (MRTP) rule
  - Tobacco Product Manufacturing Practice (TPMP) rule
  - PMTA for ENDS Final Guidance
- FDA will continue to assist manufacturers through online information, meetings, webinars, and additional guidances.