



Enforcement,
Litigation, and
Compliance
Conference
December 7-8, 2016
Washington, DC

Compliance Central with FDA Center Compliance Directors: Part II

Daniel McChesney, Director, Office of Surveillance and Compliance,
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Moderated by: Miriam Guggenheim, Partner, Covington & Burling LLP

FDLI's Enforcement, Litigation, and Compliance Conference

Center for Tobacco Products Office of Compliance and Enforcement 2016 Update

Ann Simoneau, Director
Office of Compliance and Enforcement
Center for Tobacco Products, FDA
December 7, 2016



Final Deeming Regulation

On May 10, 2016, FDA published a final 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; and
- Future tobacco products.

Final Deeming Regulation

- Automatic provisions: provisions in the FD&C Act and implementing regulations that generally apply to “tobacco products” extend to and automatically apply to newly deemed tobacco products.
- Examples: establishment registration, product and ingredient listing, user fees for certain products, premarket review and authorization of new tobacco products, adulteration and misbranding.
- The final Deeming rule is a foundational regulation. FDA can now use its authorities in Chapter IX of the FD&C act to issue future regulations that would extend to newly deemed products.

Final Deeming Regulation – Effective and Compliance Dates

www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM501016.pdf

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

CENTER FOR 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			



Guidances – Deeming (5/5/16)

- Tobacco Product Master Files
- Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) Draft Guidance
- 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
- Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Other Guidances

- Listing of Ingredients in Tobacco Products (*Revised) - Draft Guidance - 10/28/16
- Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016 During the Deeming Compliance Periods - 10/12/16
- Health Document Submission Requirements for Tobacco Products (*Revised) - Draft Guidance - 09/09/16
- Submission of Warning Plans for Cigars - Draft Guidance - 08/31/16
- “Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised*) - 08/31/16
- Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*)- 07/15/16
- Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised*) - 07/15/16

Other Regulations

- Refuse To Accept Procedures for Premarket Tobacco Product Submissions – Proposed Rule (8/8/2016)
- Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco – Final Rule (05/05/16)

Enforcement: Joint CTP/CDER WL

- www.smokers-mall.com
- Flavored cigarette violations- Section 907(a)(1)(A)
- Modified Risk Tobacco Product violations – Section 911(b)(2)(A)(ii)
- Unapproved New Drug violations – Section 505 and 301(d) of the FD&C Act

Enforcement: Deeming

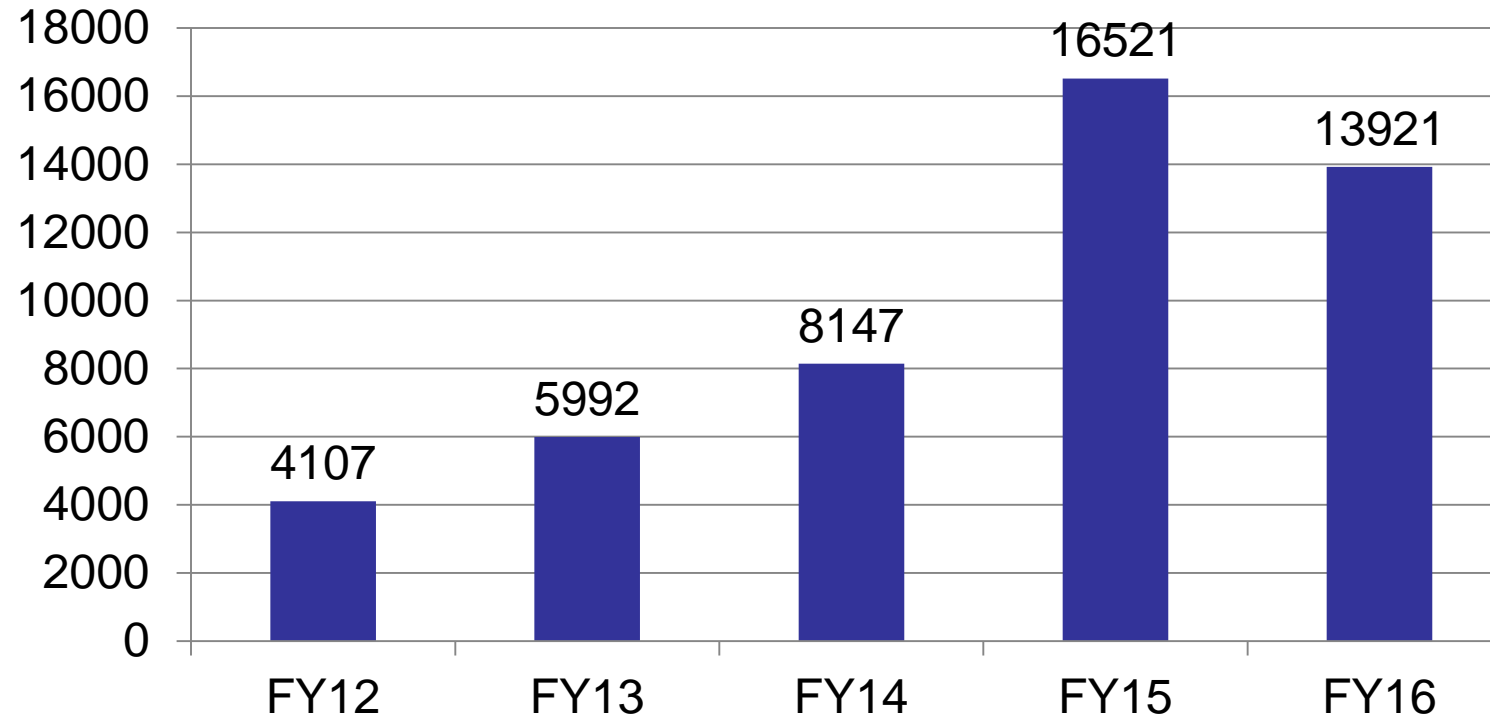
- September 2016 – First 55 Warning Letters issued to retailers for selling newly regulated tobacco products to minors.
- Warning Letters were sent to national retail chains, tobacco specialty stores, and online retailers.
- Minors were able to purchase cigars, e-cigarettes and e-liquid tobacco products, some containing flavors that appeal to youth.

Retailer Compliance Check Inspection Program

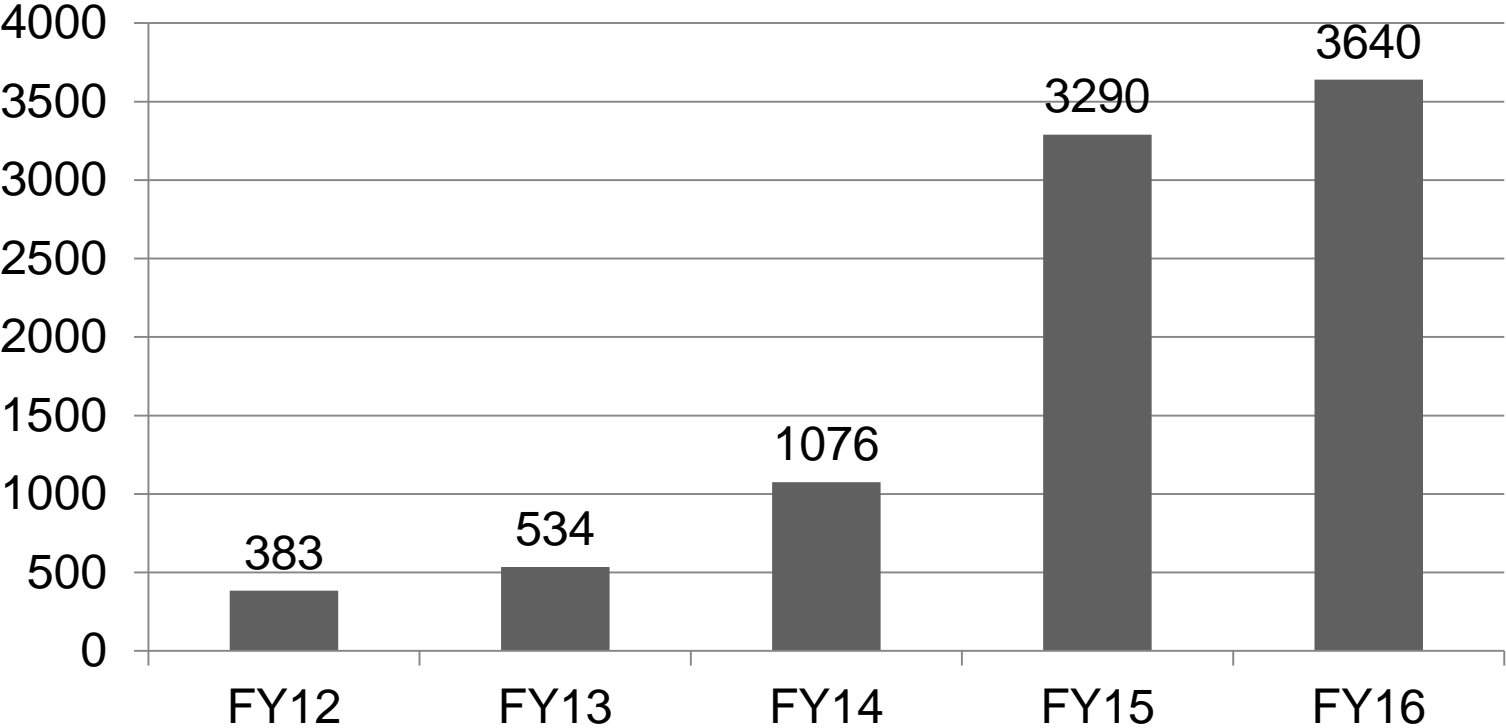
FY16 Results

- Contracts with 52 jurisdictions
- Contracts with tribes
- FDA uses its own inspectors in areas without contracts
- Over 165,000 inspections completed in FY16

Enforcement: Warning Letters Issued



Enforcement: CMPs Issued



Enforcement: No Tobacco Sale Orders

- FY16 – 31 NTSO Complaints filed.
- One retailer received a second NTSO Complaint.
- All NTSO Complaints issued by FDA are on the FDA website along with the dates of the orders issued by the ALJ as a result of settlements reached between retailers and FDA.

Internet Surveillance and Enforcement

Warning Letters Issued:

- Sale of tobacco products to minors
- Modified risk tobacco products
- Flavored cigarettes
- Smokeless tobacco product warning statements
- FDA Approved claims

Compliance Webinars



[New Regulatory Requirements for Vape Shops](#) (26:22)
[Download Slides](#)



[New Regulatory Requirements for Tobacco Manufacturers and Importers](#) (37:28) [Download Slides](#)



[New Regulatory Requirements for Tobacco Retailers](#) (25:49)
[Download Slides](#)

- 15 new Webinars for FY available on FDA website to assist newly regulated industry with compliance.

Focus for 2017

- Monitor for compliance with new regulatory requirements as they become effective under the deeming regulation.
- Expand domestic manufacturer and retailer inspections to include newly regulated tobacco products.

Center for Veterinary Medicine: Enforcement Priorities and Actions

By

Daniel G. McChesney, Ph.D.

Director

Office of Surveillance and Compliance

Center for Veterinary Medicine

To

FDLI Enforcement Conference

Compliance Central-Part II

December 7 , 2016



OSC: 2017 Priorities

- Implement labeling changes in response to guidance 213
- Implement VFD regulations
- Publish revised Section 105 report with sales and species data
- Publish revised Compounding GFI
- Complete review and proposed list (Appendix A) of BDS permitted for compounding office stock

OSC: 2017 Priorities

- Address post-approval safety concerns and shortages
- Support drug approval process by addressing competing unapproved and/or compounded products

OSC 2017 Priorities

- Implement Animal Preventive Controls rule in the animal food industry
- Develop multiple guidance documents supporting implementation of Animal PC

Compliance Actions 2016

- **Compliance Regulatory Cases FY2016**
- 4 Injunctions
- 62 W/Ls
 - 44 Tissue Residue
 - 18 Post Market Compliance
- 11 Untitled Letters 7 letters downgrade from W/L

Compounding

- Revised Draft GFI 230 under FDA review
- Coverage
 - Dogs, cats, horses (GFI 230)
 - Food animals (GFI 244)
 - Minor species non-food animals (pending)
- Influencers of who can provide/compound
 - Different governing regulation animal vs. human
 - Inherent conflicts because of different needs and models for delivering care (e.g. DQSA, AMDUCA, limited availability of drugs for animals, third party payers, human food safety)
- Potential Providers
 - Pharmacies, veterinarians for specific patient
 - Veterinarians, pharmacists, or pharmacies for office stock from a limited list of BDS populated by CVM

Support of the Approval Process

Unapproved Levothyroxine Products

- In Jan 2016, following the first approval for replacement therapy for diminished thyroid function (commonly known as hypothyroidism) in dogs, 6 warning letters were issued by FDA to companies marketing unapproved animal drugs containing levothyroxine for use in dogs.
- The 6 manufacturers agreed to discontinue manufacturing, marketing, and distributing their products.

Unapproved Levothyroxine Products Follow-up Actions

- Discontinuation of offering products for sale
- Products removed from websites
- We continue to investigate those marketing unapproved animal drugs.

Thank you

