FDA'S IMPORT OPERATIONS: HOW FDA REGULATES IMPORTED PRODUCTS

Presented by
Office of Regulatory Affairs
Office of Compliance and Enforcement

October 2016

PRESENTATION OVERVIEW

General Overview of FDA and Import Law

- What we regulate
- "appears" and "or otherwise"
- Section 801 of FD&C Act

The Import Process

- Entry Review
- Examinations / Samples
- Import Alerts
- Detentions
- Refusals
- Product Codes

PRODUCTS REGULATED BY FDA

- Tobacco Products
- Human foods (exceptions: most meat and poultry)
- Animal feeds
- Cosmetics
- Drugs (both human and animal)
- Biologics (including human cells and tissues)
- Medical devices
- Electronic products that emit radiation

FDA AND IMPORTS

- FDA provides consumer protection by enforcing the Federal Food Drug & Cosmetic Act (FD&C Act), among other laws
- Imports are primarily addressed in FD&C Act section 801
- 801: Imported FDA-regulated products are subject to refusal of admission for appearing to be adulterated or misbranded based on evidence

ADULTERATION AND MISBRANDING

Adulterated tobacco products are defined in Section 902 of the FD&C Act.

Example: A tobacco product that consists in whole or in part of any filthy, putrid, or decomposed substance.

Misbranded Tobacco products are defined in section 903 of the FD&C Act.

Example: A tobacco product with labeling that is false or misleading in any particular.

FDA IMPORT LAW: FD&C ACT SECTION 801

- FDA has jurisdiction over the products it regulates through the FD&C Act

- 801 applies to those products at the time of entry

FDA IMPORT LAW: FD&C ACT SECTION 801

- "If it appears from the examination of such samples or otherwise that…"
  - such article has been manufactured, processed, or packed under insanitary conditions… or
  - such article is forbidden or restricted in sale in the country in which it was produced … or
  - such article is adulterated, misbranded, or in violation of section 505 (New Drugs)
- "then such article shall be refused admission…"

FOOD DRUG & COSMETIC ACT
FDA CHAPTER VIII – IMPORTS AND EXPORTS

"appears" – provides FDA's standard of proof

We can refuse entry to goods that:

- Appear to be adulterated or misbranded
- Appear to be unapproved new drugs
- Appear to have been manufactured not in accordance with GMPs

FOOD DRUG & COSMETIC ACT
FDA CHAPTER VIII – IMPORTS AND EXPORTS

"or otherwise" – allows FDA to make admissibility decisions using:

- Historical data
- Examinations (vs. sample collections)
- Information from other sources
- Other evidence

THE IMPORT PROCESS

US Customs and Border Protection (CBP) has authority for all imported products:

- Entry is made to CBP
- If FDA regulated, CBP forwards to FDA
- FDA then begins its admissibility process

THE IMPORT PROCESS: ENTRY REVIEW

Entry Reviewers

- FDA has trained individuals who review entry declarations and evaluate the admissibility of a product.
- Entry reviewers have several options:
  - Release the product
  - Request examination of the product
  - Request additional information or documents
  - Recommend detention of the product

THE IMPORT PROCESS: RELEASE

- Product may be distributed
- FDA still has jurisdiction
- Does not preclude FDA action if a problem is found later

THE IMPORT PROCESS: DETENTION

- In this context, FDA “detention” is an administrative process
  - NOT a physical hold of the product
  - Importer often takes possession of the articles
- FDA can detain based upon “appearance” of a violation
  - Importer has the right to give evidence to refute this appearance
  - This is known as the “Detention and Hearing Process”
- After considering any such evidence, the detention will either stand (refusal) or be overturned (release)

THE IMPORT PROCESS: DETENTION

- FDA Detention Notice to importer and consignee
  - Indicates our belief the articles are subject to refusal
  - Reason(s) why
  - Right to provide testimony (evidence)
  - Timeframe for response
  - Contact name/number

THE IMPORT PROCESS: DETENTION

- In some circumstances, the importer can also petition to recondition the goods to bring them into compliance
  - Relabeling a misbranded product
  - Correcting an adulterated product
  - Making a product not FDA regulated

- Reconditioning must be approved by FDA

THE IMPORT PROCESS: EXAMINATIONS

- Field personnel will examine for evidence of (among other things):
  - Filth
  - Decomposition
  - Packaging defects
  - Mishandling of products
  - Misbranding

- Examinations may uncover “appearance” of violations

THE IMPORT PROCESS: EXAMINATIONS

Investigators/Inspectors

- Go out to the port or destination and conduct an examination of the shipment, which may include a label review or sample collection.
- If a sample is collected, it is packaged and shipped to the appropriate laboratory for analysis.
- The appropriate documentation is completed and data recorded in FDA's database.

THE IMPORT PROCESS: LABORATORY ANALYSIS

Laboratory Analyst

- The laboratory receives samples from the field and perform the appropriate analysis.

- Analysts record their findings in the appropriate database.

THE IMPORT PROCESS: EXAMINATIONS/SAMPLE COLLECTIONS

- If apparent violations are discovered
  - Detention and Hearing Process begins

- If no violations are discovered
  - FDA Release

THE IMPORT PROCESS: REFUSAL OF ADMISSION

- If a detained product can not be brought into compliance, FDA will refuse entry
- Refused product may be exported or destroyed
- Civil Money Penalties if products are not exported or destroyed
- FDA does have authority to seize product if certain criteria have been met

IMPORT ALERTS

- Historical data showing:
  - Commodities
  - Manufacturers/shippers
  - Countries of origin
  - Or combinations of the above
- Appear to be producing or shipping products that violate the FD&C Act

- http://www.accessdata.fda.gov/cms_ia/ialist.html

IMPORT ALERTS

- Provide information to the field offices
- Field can use this information to detain goods without examining them
- Keep FDA from having to sample over and over again
- Noncompliant products may be placed and stay on an Import Alert until the product comes into compliance, and firms importing violative products may be placed and stay on import alert until the firm demonstrates that it can produce a compliant product.

CURRENT INDUSTRY WIDE TOBACCO IMPORT ALERTS

1. Cigarettes or any component parts which contain a characterizing flavor other than tobacco or menthol
2. Cigarettes, cigarette tobacco, smokeless tobacco or roll-your-own tobacco which are labeled or advertised using the descriptors light, low, or mild without an authorizing FDA order
3. Smokeless Tobacco Products Without Required Warning Label
4. Tobacco Products Found to be Not Substantially Equivalent
5. Regulated Tobacco Products for Non Payment of User Fees

PRODUCT CODES

- The product codes for Tobacco Products are available in the Product Code Builder
- The industry code for Tobacco Products is 98
- The product code builder link is: http://www.fda.gov/ForIndustry/ImportProgram/ProductCodeBuilderforFoods/default.htm

COMPLIANCE TRAINING FOR SMALL BUSINESSES:

IMPORTING TOBACCO PRODUCTS

October 2016

AGENDA

Scope

Background

Selected Statutory Provisions

Resources for Tobacco Product Importers

SCOPE

- This presentation covers selected issues, provisions, and resources related to tobacco product imports

- For more information regarding other regulatory requirements please visit our webpage at www.FDA.gov/TobaccoProducts/

- Deeming specific information can be found at www.FDA.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm388395.htm

BACKGROUND: APPLICABLE LAW

- On June 22, 2009, the President signed into law the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)
- The Tobacco Control Act granted FDA new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors

BACKGROUND: APPLICABLE LAW

- In addition to amending the Food, Drug, and Cosmetics Act (FD&C Act), the Tobacco Control Act also amended:
  - the Federal Cigarette Labeling and Advertising Act (FCLAA)
  - the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA)

FDA'S REGULATION OF TOBACCO PRODUCTS

The Federal Food, Drug, and Cosmetic Act (FD&C Act):

- Gives the Food and Drug Administration (FDA) immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and other tobacco products that the agency, through regulation, deems to be subject to its tobacco product authorities.

- The Final Deeming rule, which went into effect August 8, 2016, deems all products that meet the definition of a tobacco product under section 201(rr) of the FD&C Act, including components and parts, **except** accessories of those newly deemed products, subject to FDA's tobacco product authorities.

FINAL DEEMING RULE

Finished Tobacco Products

- A tobacco product, **including** all components and parts, sealed in final packaging intended for consumer use.
- Examples: Pipe Tobacco, Cigars, Electronic Nicotine Delivery Systems, Cigar Tobacco Filler, Hookah Tobacco, Filters, Cigars Tips, and e-liquid flavor cartridges sold separately to consumers.

Covered Tobacco Products

- All newly regulated tobacco products **excluding** components and parts not made or derived from tobacco.
- Examples: Pipe Tobacco, Cigars, Liquid Nicotine, Cigar Tobacco Filler, and Hookah Tobacco.

BACKGROUND

- Importers may be distributors, tobacco product manufacturers, or both
- **Distributor** – Section 900(7) FD&C Act

  "any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption"
- **Tobacco Product Manufacturer** – Section 900(20) FD&C Act includes "any person who … imports a finished tobacco product for sale or distribution in the United States"

BACKGROUND: REQUIREMENTS FOR IMPORTED TOBACCO PRODUCTS

- Imported tobacco products are required to meet the same standards and requirements as domestic tobacco products

- Compliance, Enforcement and Training webpage at: www.FDA.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm

STATUTORY PROVISIONS: TOBACCO PRODUCT STANDARD – FLAVORED CIGARETTES

- Section 907(a)(1)(A) FD&C Act bans cigarettes and its component parts (e.g. cigarette tobacco) from containing any characterizing flavor, other than tobacco or menthol flavor.
  - For example: strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee
- Cigarettes containing a prohibited characterizing flavor are adulterated and are subject to refusal

STATUTORY PROVISIONS: SMOKELESS TOBACCO WARNING REQUIREMENTS

- Smokeless tobacco product packages and advertising must carry one of four required warning statements found in CSTHEA (15 U.S.C. Section 4402)
  - WARNING: This product can cause mouth cancer.
  - WARNING: This product can cause gum disease and tooth loss.
  - WARNING: This product is not a safe alternative to cigarettes.
  - WARNING: Smokeless tobacco is addictive.

STATUTORY PROVISIONS: WARNING PLANS FOR SMOKELESS TOBACCO PACKAGES AND ADVERTISEMENTS

A tobacco product manufacturer, importer, distributor, or retailer, must follow an FDA-approved warning plan that covers:

(1) The equal distribution and display of the required warning statements on packaging for each brand of product and

(2) The quarterly rotation, in alternating sequence, of the required warning statements in advertisements for each brand of product

STATUTORY PROVISIONS: MODIFIED RISK TOBACCO PRODUCTS (MRTP)

- An MRTP is a tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

- No person may introduce or deliver for introduction into interstate commerce any MRTP unless an order issued pursuant to section 911(g) is in effect with respect to such product. (Section 911(a) FD&C Act)

STATUTORY PROVISIONS: ESTABLISHMENT REGISTRATION

- Establishments engaged in the manufacture, preparation, compounding, or processing* of tobacco products must be registered with FDA
  - Currently only applies to domestic establishments
  - Establishments which manufacture, prepare, compound, or process newly deemed products must be registered by December 31, 2016.

*Note – Importers who repackage or otherwise change the container, wrapper, or label of any tobacco product package must register

STATUTORY PROVISIONS: LISTING OF INGREDIENTS

- A manufacturer or importer shall submit an ingredient list including:
  - Tobacco, substances, compounds, and additives that are added to the tobacco, paper, filter, or other part of each tobacco product by brand - Section 904(a)(1) of the FD&C Act
  - Either a foreign manufacturer or importer may submit the required ingredient listing.

WHAT REQUIREMENTS APPLY TO TOBACCO PRODUCT MANUFACTURERS?

Requirements for Finished Tobacco Products

Requirement and Authority	Compliance Date	Compliance Date for Small-Scale Tobacco Product Manufacturers
Ingredient listing (FD&C Act §904)	Deeming Rule Effective Date + 6 months (February 8, 2017)	Deeming Rule Effective Date + 12 months (August 8, 2017)
Tobacco health documents submissions (FD&C Act §904)	Deeming Rule Effective Date + 6 months (February 8, 2017)	Deeming Rule Effective Date + 12 months (August 8, 2017)
Harmful and potentially harmful constituent (HPHC) testing and reporting (FD&C Act §904, §915)	Deeming Rule Effective Date + 3 years (August 8, 2019)	Deeming Rule Effective Date + 3 year (August 8, 2019)
Registration of establishments and listing of products (FD&C Act §905)	Initial Registration and Listing On or Before December 31, 2016	Initial Registration and Listing On or Before December 31, 2016

WHAT REQUIREMENTS APPLY TO TOBACCO PRODUCT IMPORTERS?

Requirements for Importers of Finished Tobacco Products

Requirement and Authority	Compliance Date	Compliance Date for Small-Scale Tobacco Product Manufacturers
Ingredient listing (FD&C Act §904)	Deeming Rule Effective Date + 6 Months (February 8, 2017)	Deeming Rule Effective Date + 12 months (August 8, 2017)
Tobacco health documents submissions (FD&C Act §904)	Deeming Rule Effective Date + 6 months (February 8, 2017)	Deeming Rule Effective Date + 12 months (August 8, 2017)
Harmful and potentially harmful constituent (HPHC) testing and reporting (FD&C Act §904, §915)	Deeming Rule Effective Date + 3 years (August 8, 2019)	Deeming Rule Effective Date + 3 year (August 8, 2019)

WARNING REQUIREMENTS FOR CIGARETTE TOBACCO, RYO TOBACCO, AND COVERED TOBACCO PRODUCTS* (21 CFR PART 1143)

Requirement	Effective Date – Stop Manufacture	Effective Date – Stop Distribution
Addictiveness warning statement on packaging	Publication Date of Deeming Rule + 24 months (May 10, 2018)	Publication Date of Deeming Rule + 25 months (June 11, 2018)
Addictiveness warning statement on advertising	Publication Date of Deeming Rule + 24 months (May 10, 2018)	Publication Date of Deeming Rule + 24 months (May 10, 2018)

"WARNING: This product contains nicotine. Nicotine is an addictive chemical."

*The addictiveness warning is only one of the six required warning statements for cigars.

WARNING STATEMENT REQUIREMENTS

- Addictiveness warning required on all cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and advertisements.
  - "WARNING: This product contains nicotine. Nicotine is an addictive chemical."
- Product package: 2 principal display panels (PDP); warning area shall comprise at least 30% of each PDP.
- Advertisement: occupy at least 20% of the upper portion of the ad.
- Specific format, layout, and marketing requirements (like the requirements for smokeless tobacco).

WARNING STATEMENTS — CIGARETTE TOBACCO, RYO TOBACCO, AND COVERED TOBACCO PRODUCTS OTHER THAN CIGARS (21 CFR 1143.3)

- Self certification submission to FDA for tobacco products that are made or derived from tobacco but do not contain nicotine.
  - These products must include the statement on their packages and advertising – “This product is made from tobacco.”
- Small product packages – tobacco product packages that are too small to bear the required warning label statement, the warning may be displayed on a tag permanently affixed to the tobacco product package.

WARNING STATEMENTS—CIGARS (21 CFR 1143.5)

CIGAR WARNING STATEMENTS	
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.
WARNING: Cigar use while pregnant can harm you and your baby. Or SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.	WARNING: This product contains nicotine. Nicotine is an addictive chemical.

CIGAR WARNING PLANS

- Regulation includes marketing requirements for the random display and distribution of the cigar warning statements on product packages and quarterly rotation in advertisements in accordance with an FDA-approved warning plan.

- Submission deadline for cigar warning plans by applicable manufacturers, distributors, importers, and retailers:
  - One year after the date of publication of the final rule, however, firms may submit earlier.

WARNING STATEMENTS – CIGARETTE TOBACCO, RYO TOBACCO, AND COVERED TOBACCO PRODUCTS

- Warning statement effective dates:
  - 24 months after the publication date of the rule (May 10, 2018), packages of newly manufactured products and all advertisements must display the new warning(s);
  - 25 months after the publication date of the rule (June 11, 2018), manufacturers must include the new warning(s) on packages of products introduced into domestic commerce, regardless of the date of manufacture.

WHAT REQUIREMENTS APPLY TO TOBACCO PRODUCT MANUFACTURERS AND IMPORTERS?

Label, Labeling, and Advertising Provisions for All Newly Regulated Tobacco Products.

Requirement and Authority	Compliance Date
Prohibition on false or misleading statements on labeling or in ads (FD&C Act §§903(a)(1) and (a)(7)(A))	Publication Date of Deeming Rule + 90 days (August 8, 2016)
Required label statements for products in package form (FD&C Act §903(a)(2)): • The name and place of business of the tobacco product manufacturer, packer, or distributor; • An accurate statement of the quantity of the contents; • An accurate statement of the percentage of domestic and foreign grown tobacco; and • The statement "Sale only allowed in the United States."	Publication Date of Deeming Rule + 24 months (May 10, 2018)
Prominent placement and conspicuousness of labeling statements (FD&C Act §903(a)(3))	Publication Date of Deeming Rule + 90 days + 1 year (August 8, 2017)
Required statements on labels and ads (FD&C Act §§903(a)(4) and (a)(8)) (established name, relevant warnings)	Publication Date of Deeming Rule + 24 months (May 10, 2018)

USER FEE FINAL RULE

User Fees

- The rule requires cigar and pipe tobacco manufacturers and importers to pay user fees in accordance with Section 919 of the Tobacco Control Act.

RESOURCES FOR TOBACCO PRODUCT IMPORTERS

Guidance, Compliance & Regulatory Information for tobacco products

http://www.fda.gov/TobaccoProducts/Labeling/Default.htm

- Guidance documents

http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm

Regulatory Procedures Manual

- Chapter 9 – Import Operations and Actions

http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179264.htm

RESOURCES FOR TOBACCO PRODUCT IMPORTERS

- CTP Website available at:
  - http://www.fda.gov/TobaccoProducts/default.htm
- For General Inquiries contact via email or phone:
  - AskCTP@fda.hhs.gov
  - 1-877-CTP-1373
- Inquiries from small businesses
  - Smallbiz.tobacco@fda.hhs.gov
- Sign up for weekly updates available at:
  - http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm