REGISTRATION AND PRODUCT LISTING REQUIREMENTS FOR DOMESTIC ESTABLISHMENTS

Presented by
Office of Compliance and Enforcement
Center for Tobacco Products

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

October 2016

AGENDA

A. **FDA Overview**
   - FDA Regulation of Tobacco Products
   - Compliance Policies
B. **Who Has to Submit**
C. **When to Submit**
D. **What Information to Include**
E. **How to Submit**
F. **Additional Resources & Questions**

FDA REGULATION OF TOBACCO PRODUCTS

- The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) giving the Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Act also granted FDA the authority to deem other tobacco products subject to the law, through regulation.

- The Deeming rule, published on May 10, 2016 (effective August 8, 2016) extends FDA's tobacco product authorities in Chapter IX of the FD&C Act to include all products that meet the definition of a tobacco product under section 201(rr) of the FD&C Act, except accessories of those newly deemed products.

FDA REGULATION OF TOBACCO PRODUCTS

- Under section 905 of the Tobacco Control Act, every person who owns or operates any domestic establishments engaged in the manufacture, preparation, compounding, or processing of a regulated tobacco product must register those establishments with FDA by December 31 of each year.

- All registrants must also submit a list of all tobacco products which are being manufactured by that person for commercial distribution, along with certain accompanying information including all labeling.

R&L COMPLIANCE POLICY: NEWLY DEEMED TOBACCO PRODUCTS

Compliance Policy:

- At this time, FDA intends to enforce the registration and listing requirements of section 905 with respect to ***finished tobacco products only***. FDA does not, at this time, intend to enforce these requirements with respect to products that are sold or distributed solely for further manufacturing.

FDA intends to the use the following definitions in implementing the establishment registration and product listing requirements of section 905:

- ***Finished tobacco product*** means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use.
- ***Components and parts*** that are sold separately from other tobacco products are also finished tobacco products if they are sold in final packaging intended for consumer use.

REGISTRATION – DEFINITIONS FDA INTENDS TO USE

- **"Owner" -** person who has an ownership interest in an establishment.

- **"Operator" -** person who has management authority over an establishment.

- **"Establishment"** - place of business under one ownership at one general physical location. A single building may house more than one distinct establishment if the establishments are under separate ownership.

REGISTRATION – WHO MUST REGISTER WITH FDA?

(Need all 3 for R&L to apply!)

1. **Owner or Operator** of any
2. Establishment **located in the United States** that is
3. Engaged in **any** of the following **tobacco product activities**:

- MANUFACTURING
- PREPARING
- COMPOUNDING
- PROCESSING
- REPACKAGING (or otherwise changing the container, wrapper, or labeling)

REGISTRATION – COMMON ISSUES

- Owners and Operators of these tobacco product establishments, do not need to register with FDA at this time:

  - **Importers** who do not own or operate a domestic establishment engaged in the manufacture, preparation, compounding or processing of a tobacco product, and

  - **Foreign Manufacturers***

  * FDA has announced its intent to issue a rule regarding registration and listing, including application of the requirements to foreign manufacturers, in the Unified Agenda (RIN No. 0910-AG89).

REGISTRATION – COMMON ISSUES (CONTINUED)

Contract Manufacturers

- An owner or operator may authorize a third party agent to register and submit product listing information on its behalf.

- In the contract scenario, **Company A** hires **Company B** to manufacture **Company A's** tobacco product. If the hired party (**Company B**) is the manufacturer of the tobacco product, then that party is responsible for both the registration and product listing submissions. However, the hiring party (**Company A**), if authorized, may act as **Company B's** agent by submitting on behalf of **Company B's** owner or operator.

PRODUCT LISTING – WHO MUST REPORT TO FDA?

Required to Register = Required to List

- All registrants must submit a list of all tobacco products that are being manufactured by the registrant for commercial distribution.
- In implementing the registration and listing requirements for tobacco products, FDA intends to define **"Commercial Distribution"** as any distribution of a tobacco product to consumers or to another person for further manufacturing through sale or otherwise.
- FDA intends to enforce the registration and product listing requirements of section 905 with respect to ***finished tobacco products only***.

REGISTRATION & PRODUCT LISTING – WHEN TO SUBMIT?

- **Register Annually** – before December 31st of each year
- **Product Listing Biannually –** during June and December each year
  - At the time of *first registration*, you should list *all establishments* you own or operate that are engaged in the manufacture of a tobacco product.
  - At the same time, you should file a complete list of *all tobacco products* which are being manufactured by you for commercial distribution.
  - Registration information must be *resubmitted every year*.
  - Product Listing updates must be *submitted twice each year* (June & December)
- For newly regulated products, domestic establishments engaged in the manufacture will be required to register and submit product listing by December 31, 2016.

PRODUCT LISTING – BIANNUAL UPDATES

- **Section 905(i)(3)** requires that certain changes to your product list be reported twice per year - in June and December

- **What kinds of changes do I report biannually?**
  1. Any products introduced for commercial distribution that have not been included on a previous list;
  2. Any products that you have discontinued manufacturing, preparing, compounding, or processing for commercial distribution;
  3. Any products that you have resumed manufacturing, preparing, compounding, or processing for commercial distribution after previously reporting them as discontinued ; and
  4. Any material change to information previously submitted.

REGISTRATION – WHAT'S INCLUDED?

Required Registration Information:

- Name and full address of each establishment engaged in manufacturing the registrant owns or operates.
- Name and places of business of the owner or operator.
  - If partnership = name of each partner
  - If corporation = name of each corporate officer and director AND the State of incorporation

Requested Registration Information:

- E-mail address
- Data Universal Numbering System (D-U-N-S) number

PRODUCT LISTING – WHAT'S INCLUDED?

Required Product Listing Information

If product is subject to:

- tobacco product standard (section 907 of the FD&C Act)

OR

- to premarket review (section 910 of the FD&C Act)

THEN

Product listing must include:

- a reference to the authority for the marketing of the tobacco product and a copy of all labeling for that product.
- We interpret this to mean that labeling is to be submitted as an exact, legible, full color copy.

PRODUCT LISTING – WHAT'S INCLUDED? (CONTINUED)

For all other tobacco products:

- All labeling for that product
- A "representative sampling of advertisements"
- A "copy of all consumer information"

❖ "**Copy of All Consumer Information**" is required to the extent the information is not advertising and has not already been provided as a form of product labeling. Consumer information does not include information directed at wholesalers, distributors or retailers, where such information is not available to consumers.

❖ **"Representative Sampling of Advertisements" –** We interpret this to means typical advertising material that reflects the full range of promotional statements made for the tobacco product.

SUBMITTING REGISTRATION AND PRODUCT LISTING

Two Ways to Submit:

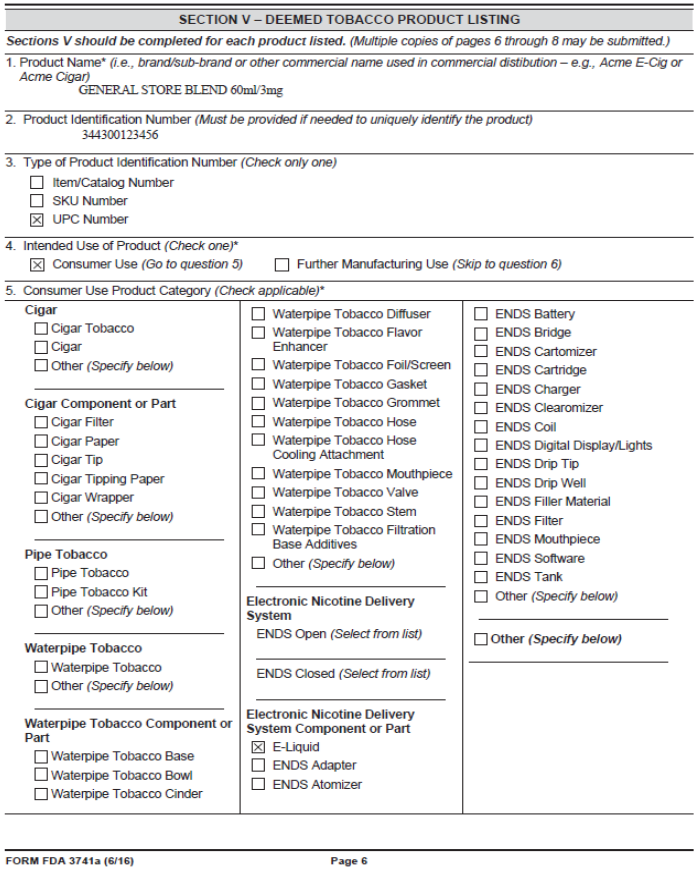
1. **Online** - The FDA Unified Registration and Listing System (FURLS) allows you to submit and view online.
   - To create an account go to: https://www.access.fda.gov/oaa/

2. **Mail** – Form FDA 3741, Form FDA 3741a
   - To download these forms, go to: http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/Tobacco/default.htm
   - Then mail the completed form to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring MD 20903-9002

PLACE HOLDER FOR NEW R&L FORM

E-Liquid - Form FDA 3741a (pg. 6)



SECTION V – DEEMED TOBACCO PRODUCT LISTING

Sections V should be completed for each product listed. *(Multiple copies of pages 6 through 8 may be submitted.)*

1. Product Name* *(i.e., brand/sub-brand or other commercial name used in commercial distibution – e.g., Acme E-Cig or Acme Cigar)*
   GENERAL STORE BLEND 60ml/3mg
2. Product Identification Number *(Must be provided if needed to uniquely identify the product)*
   344300123456
3. Type of Product Identification Number *(Check only one)*
   - ☐ Item/Catalog Number
   - ☐ SKU Number
   - ☒ UPC Number
4. Intended Use of Product *(Check one)**
   - ☒ Consumer Use *(Go to question 5)*
   - ☐ Further Manufacturing Use *(Skip to question 6)*
5. Consumer Use Product Category *(Check applicable)**

Cigar
- ☐ Cigar Tobacco
- ☐ Cigar
- ☐ Other *(Specify below)*

Cigar Component or Part
- ☐ Cigar Filter
- ☐ Cigar Paper
- ☐ Cigar Tip
- ☐ Cigar Tipping Paper
- ☐ Cigar Wrapper
- ☐ Other *(Specify below)*

Pipe Tobacco
- ☐ Pipe Tobacco
- ☐ Pipe Tobacco Kit
- ☐ Other *(Specify below)*

Waterpipe Tobacco
- ☐ Waterpipe Tobacco
- ☐ Other *(Specify below)*

Waterpipe Tobacco Component or Part
- ☐ Waterpipe Tobacco Base
- ☐ Waterpipe Tobacco Bowl
- ☐ Waterpipe Tobacco Cinder
- ☐ Waterpipe Tobacco Diffuser
- ☐ Waterpipe Tobacco Flavor Enhancer
- ☐ Waterpipe Tobacco Foil/Screen
- ☐ Waterpipe Tobacco Gasket
- ☐ Waterpipe Tobacco Grommet
- ☐ Waterpipe Tobacco Hose
- ☐ Waterpipe Tobacco Hose Cooling Attachment
- ☐ Waterpipe Tobacco Mouthpiece
- ☐ Waterpipe Tobacco Valve
- ☐ Waterpipe Tobacco Stem
- ☐ Waterpipe Tobacco Filtration Base Additives
- ☐ Other *(Specify below)*

Electronic Nicotine Delivery System

ENDS Open *(Select from list)*

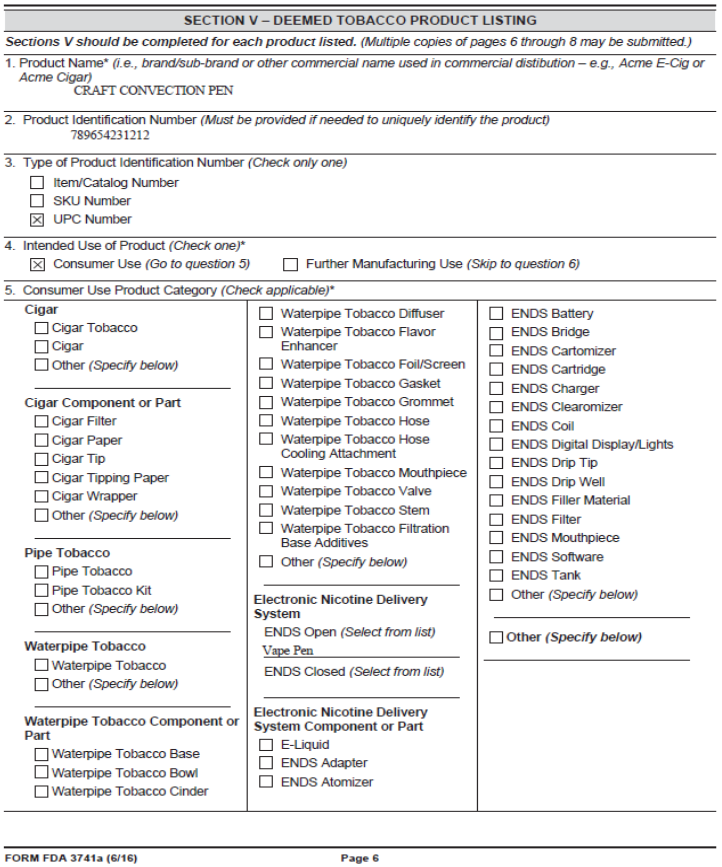
ENDS Closed *(Select from list)*

Electronic Nicotine Delivery System Component or Part
- ☒ E-Liquid
- ☐ ENDS Adapter
- ☐ ENDS Atomizer
- ☐ ENDS Battery
- ☐ ENDS Bridge
- ☐ ENDS Cartomizer
- ☐ ENDS Cartridge
- ☐ ENDS Charger
- ☐ ENDS Clearomizer
- ☐ ENDS Coil
- ☐ ENDS Digital Display/Lights
- ☐ ENDS Drip Tip
- ☐ ENDS Drip Well
- ☐ ENDS Filler Material
- ☐ ENDS Filter
- ☐ ENDS Mouthpiece
- ☐ ENDS Software
- ☐ ENDS Tank
- ☐ Other *(Specify below)*

☐ Other *(Specify below)*

FORM FDA 3741a (6/16) Page 6

ENDS - Form FDA 3741a (pg. 6)



SECTION V – DEEMED TOBACCO PRODUCT LISTING

Sections V should be completed for each product listed. *(Multiple copies of pages 6 through 8 may be submitted.)*

1. Product Name* *(i.e., brand/sub-brand or other commercial name used in commercial distibution – e.g., Acme E-Cig or Acme Cigar)*
   CRAFT CONVECTION PEN
2. Product Identification Number *(Must be provided if needed to uniquely identify the product)*
   789654231212
3. Type of Product Identification Number *(Check only one)*
   - ☐ Item/Catalog Number
   - ☐ SKU Number
   - ☒ UPC Number
4. Intended Use of Product *(Check one)**
   - ☒ Consumer Use *(Go to question 5)*
   - ☐ Further Manufacturing Use *(Skip to question 6)*
5. Consumer Use Product Category *(Check applicable)**

Cigar
- ☐ Cigar Tobacco
- ☐ Cigar
- ☐ Other *(Specify below)*

Cigar Component or Part
- ☐ Cigar Filter
- ☐ Cigar Paper
- ☐ Cigar Tip
- ☐ Cigar Tipping Paper
- ☐ Cigar Wrapper
- ☐ Other *(Specify below)*

Pipe Tobacco
- ☐ Pipe Tobacco
- ☐ Pipe Tobacco Kit
- ☐ Other *(Specify below)*

Waterpipe Tobacco
- ☐ Waterpipe Tobacco
- ☐ Other *(Specify below)*

Waterpipe Tobacco Component or Part
- ☐ Waterpipe Tobacco Base
- ☐ Waterpipe Tobacco Bowl
- ☐ Waterpipe Tobacco Cinder
- ☐ Waterpipe Tobacco Diffuser
- ☐ Waterpipe Tobacco Flavor Enhancer
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- ☐ Waterpipe Tobacco Hose
- ☐ Waterpipe Tobacco Hose Cooling Attachment
- ☐ Waterpipe Tobacco Mouthpiece
- ☐ Waterpipe Tobacco Valve
- ☐ Waterpipe Tobacco Stem
- ☐ Waterpipe Tobacco Filtration Base Additives
- ☐ Other *(Specify below)*

Electronic Nicotine Delivery System

ENDS Open *(Select from list)*
Vape Pen

ENDS Closed *(Select from list)*

Electronic Nicotine Delivery System Component or Part
- ☐ E-Liquid
- ☐ ENDS Adapter
- ☐ ENDS Atomizer
- ☐ ENDS Battery
- ☐ ENDS Bridge
- ☐ ENDS Cartomizer
- ☐ ENDS Cartridge
- ☐ ENDS Charger
- ☐ ENDS Clearomizer
- ☐ ENDS Coil
- ☐ ENDS Digital Display/Lights
- ☐ ENDS Drip Tip
- ☐ ENDS Drip Well
- ☐ ENDS Filler Material
- ☐ ENDS Filter
- ☐ ENDS Mouthpiece
- ☐ ENDS Software
- ☐ ENDS Tank
- ☐ Other *(Specify below)*

☐ Other *(Specify below)*

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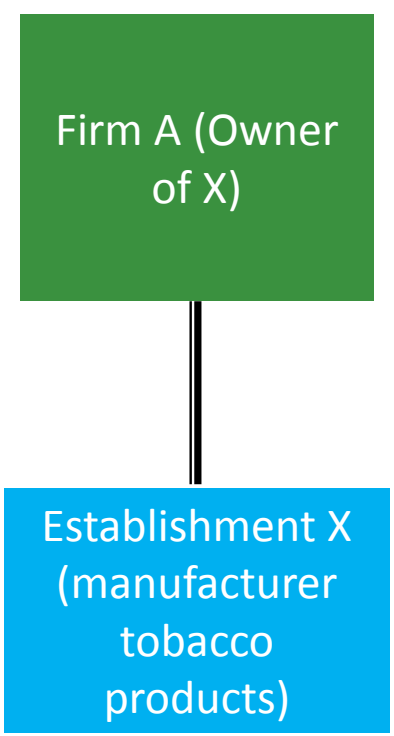
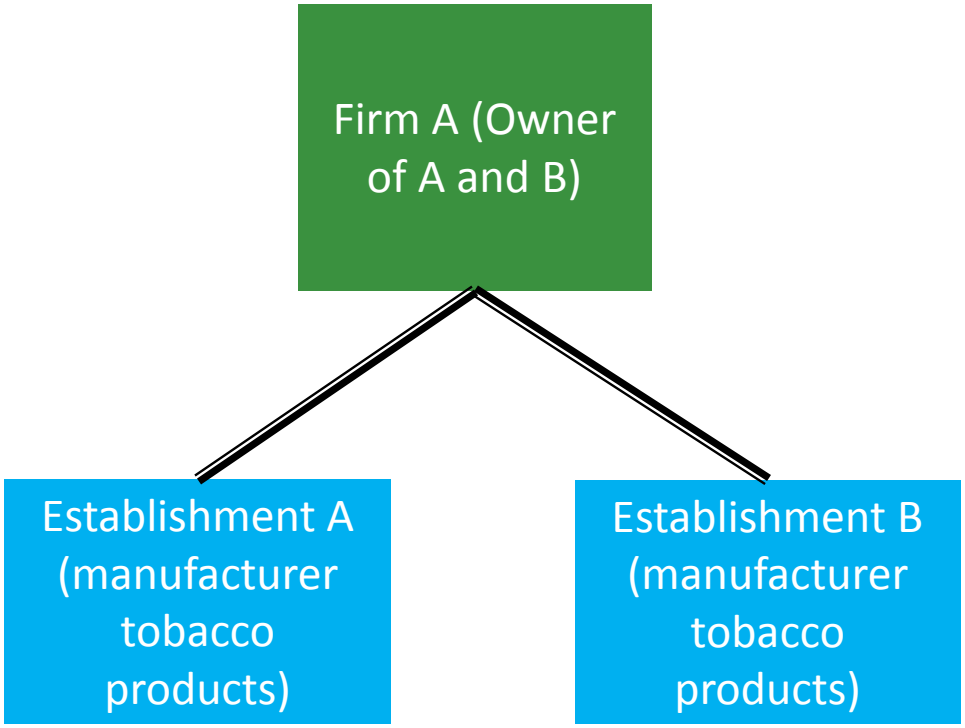
WHO MUST REGISTER AND LIST? SOME EXAMPLES





RESOURCES

FDA Manufacturer Resources:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm

Industry Guidance:
http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm

FURLS Electronic Registration Step-by-Step Instructions:
http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm386651.htm

Examples of Completed Registration and Listing Forms: Add link

FURLS Registration – Video Tutorial:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm386651.htm

Registration and Product Listing Database:
http://www.accessdata.fda.gov/scripts/ctpocerl/

QUESTIONS?

- Questions from today's webinar
- Please direct additional questions to:
  - AskCTP@fda.hhs.gov
  - CTPRegistrationandListing@fda.hhs.gov
- Thank you!

THE END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