



Establishment Registration and Product Listing Requirements

Compliance Training for Small Manufacturers

Agenda

- Background – Applicable Law
- How to Submit an Initial Registration and Product Listing
- How to Submit an Annual Registration Update
- How to Submit a Biannual Product Listing Update

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.
- FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco
- Section 905 of the Tobacco Control Act contains requirements for registering establishments and listing products

Scope

- Note that this presentation only covers establishment registration and product listing requirements
- For information about other requirements that may be applicable to your business, please visit our webpage at <http://www.fda.gov/TobaccoProducts/>

Section 905 – Registration Requirement

Who must register with the FDA?

- Every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product

What do they register?

- The name and full address of each such establishment.
- The name and places of business of the owner or operator.
- In the case of a partnership, include the name of each partner.
- In the case of a corporation, include the name of each corporate officer and director, and the State of incorporation.

Section 905 – Registration Requirement

- What is “manufacturing, preparing, compounding, or processing?”
 - This term includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user
 - For purposes of these slides, we will refer to “manufacturing, preparing, compounding, or processing” simply as manufacturing.

Section 905 – Registration Requirement

- What if an establishment changes ownership?
 - Section 905(c) of the act requires every person upon first engaging in the manufacturing of a tobacco product in any domestic establishment owned or operated by that person to register immediately as described above.
 - In addition, section 905(d) of the act requires registered owners and operators to immediately register any new establishment that begins manufacturing tobacco products.

Section 905 – Product Listing Requirement

- Who must list their products with FDA?
 - Every person who is required to register
- What products must they list?
 - All tobacco products which are being manufactured by the registrant for commercial distribution at their registered establishment

Section 905 – Product Listing Requirement

- What information must accompany a product listing?
 - If a tobacco product standard has been established under section 907 with respect to the tobacco product or the tobacco product is subject to premarket review under section 910, then you must include a reference to the authority for the marketing of the tobacco product and all labeling for that product.

Section 905 – Product Listing Requirement

For all other tobacco products, you must include:

- All copy of all labeling;
- A representative sampling of advertisements; and
- A copy of all consumer information 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.

How to Submit an Initial Registration and Product Listing

- 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

How to Submit an Annual Registration Update

- Section 905(b) requires owners and operators of establishments engaged in the manufacture of a tobacco product to register on or before December 31st of each year
- See the Guidance - Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments for more information on how to submit

How to Submit a Biannual Product Listing Update

- Section 905(i)(3) requires that certain changes to your product list be reported twice per year - in June and December
- See the Guidance - Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments for more information on how to submit

Section 905(i)(3) – Biannual Product Listing Update

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