# Guidance for Industry

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# Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

*Additional copies are available from:*
*Center for Tobacco Products*
*Food and Drug Administration*
*9200 Corporate Boulevard*
*Rockville, MD 20850*
*(Tel) 301-796-4800*
*http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Tobacco Products**

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# Guidance for Industry[1]

# Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments[2]

***This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.***

## I. Introduction

This guidance document is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. The guidance document explains, among other things:

- The statutory requirement to submit tobacco product establishment registration and product listing submissions;
- Definitions;
- Who is responsible for providing registration and product listing submissions;
- What information is included in the submissions;
- How to submit the information;
- When to submit the information; and
- FDA's compliance policies.

[1] This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.
[2] Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(h)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

# II. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Act added section 905 to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387e), establishing requirements for tobacco product establishment registration and product listing.

Section 905(b) of the act requires that "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" register with FDA the name, places of business, and all establishments engaged in these activities owned or operated by that person. Every person must register by December 31 of each year.

Section 905(i)(1) of the act requires that all registrants "shall, at the time of registration . . . file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying information, including all labeling. In addition, section 905(i)(3) of the act requires that certain changes in the product list be submitted biannually.

The failure to register in accordance with section 905 of the act, the failure to provide any information required by section 905(i), and the failure to provide a notice required by section 905(i)(3) is a prohibited act under section 301(p) of the act (21 U.S.C. 331(p)). In addition, under section 903(a)(6) of the act (21 U.S.C. 387c), a tobacco product is deemed misbranded if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905 or if it was not included in a list required by section 905(i). Violations relating to registration and product listing under section 905 are subject to regulatory and enforcement action, including, but not limited to, seizure and injunction.

# III. Discussion

FDA has developed an electronic submission tool, eSubmitter, to streamline submission and receipt of registration and product listing information required by section 905 of the act. FDA has developed a paper form (FDA Form 3741) as an alternative submission tool although FDA strongly encourages electronic submission. The eSubmitter application, technical assistance documents, and paper submission form can be accessed at http://www.fda.gov/tobacco.

## A. What definitions apply?

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

1. *Commercial Distribution*: The term "commercial distribution" includes any distribution of a tobacco product to consumers or to another person for further manufacturing through sale or otherwise. As examples, it includes the distribution of a tobacco product as a promotional sample and the delivery of a tobacco product to another manufacturer for further processing via contract without a change in the formal ownership of the product. Commercial distribution does not include internal or interplant transfer of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, and it does not include providing a tobacco product for product testing where such products are not made available for consumption or resale.
2. *Domestic Establishment*: The term "domestic establishment" means an establishment in any State or Territory or possession of the United States.
3. *Establishment*: The term "establishment" means a 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.
4. *Labeling*: The term "labeling," based on section 201(m) of the act (21 U.S.C. 321(m)), means all labels and other written, printed, or graphic matter (1) upon any tobacco product or any of its containers or wrappers, or (2) accompanying such tobacco product.
5. *Manufacturing*: The term "manufacturing" means the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package (section 905(a)(1) of the act). This term includes the activities of reconstituting and blending tobacco leaf; testing for quality control and product release; and applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. This term excludes the activities of de-stemming, drying, or packing tobacco leaf; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaf with nothing other than potable water in the form of steam or mist.
6. *Owner*: The term "owner" means a person, as defined in section 201(e) of the act (21 U.S.C. 321(e)), who has an ownership interest in an establishment.
7. *Operator*: The term "operator" means a person, as defined in section 201(e) of the act (21 U.S.C. 321(e)) who has management authority over an establishment.
8. *Pouch*: The term "pouch" means a permeable pouch, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.
9. *Tobacco Product*: The term "tobacco product" means "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)" (section 201(rr) of the act (21 U.S.C. 321(rr)). This term does not include an article that is a drug, a device, or a combination product as defined in the act (section 201(rr) of the act (21 U.S.C. 321(rr)). Thus, the term is not limited to products containing tobacco, but also includes components, parts, and accessories of tobacco products, whether they are for further manufacturing or are ready for consumer use. For example, tobacco, papers, and filters

are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

## B. Who registers and submits product listing information under section 905 of the act?

Every person who owns or operates any domestic establishment engaged in manufacturing regulated tobacco products must register under section 905(b) of the act, and every registrant must file a list of its regulated tobacco products in accordance with section 905(i) of the act. An owner or operator may authorize a third party agent to register and submit product listing information on its behalf. Registration and product listing requirements apply only to those persons who own or operate domestic establishments engaged in manufacturing tobacco products; an importer who does not own or operate such an establishment is not subject to the requirements of section 905(b) or section 905(i) of the act.

At this time, FDA intends to enforce the registration and product listing requirements with respect to:

- establishments engaged in the manufacturing of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use; and

- establishments engaged in the manufacturing of tobacco, papers, filters, or pouches, whether such products are for further manufacturing of, or for consumer use as, regulated tobacco products. This includes tobacco, papers, and filters sold separately, in kits (such as for roll-your-own tobacco), or as part of accessories.

At this time, FDA does not intend to enforce the registration and product listing requirements in other circumstances.

FDA intends to focus enforcement of the registration and product listing requirements on owners and operators engaged in the manufacture of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use, as well as owners and operators engaged in the manufacture of tobacco, papers, filters, and pouches because these comprise the principal components of most tobacco products sold to consumers. Should the agency find that additional information is needed to protect the public health, the agency may reconsider this compliance policy. We intend to communicate any such compliance policy changes by guidance and/or rulemaking.

In order to reduce redundant submissions, FDA strongly encourages that the owner act as the agent of all operators within a given business structure in submitting registration and product listing information. Under this approach, the owner would register all establishments it owns and submit the associated product listing information, and would also register on behalf of all operators with management authority over those establishments. An owner acting as the agent of one or more operators would need to submit all information required of the operator(s) (e.g., the operator(s) name and places of business), but could submit all information for both the owner and the operator(s) in a single registration. If an owner

registers/lists all of its establishments using this approach, the operators of those establishments would not need to register. For those scenarios in which an owner is also the operator of a given establishment, the owner/operator can register in a single registration.

The following example illustrates the registration and product listing requirements for a complex business structure: Firm A owns establishment X, which is engaged in manufacturing tobacco products. Firm B does not own an establishment engaged in manufacturing tobacco products. Firm A and Firm B are wholly owned subsidiaries of Holding Company C. Holding Company C does not own or operate any establishments engaged in manufacturing tobacco products. In this scenario, Firm A would be required to register establishment X and list products, but neither Firm B nor Holding Company C would be subject to registration or product listing requirements.

## C. What information is submitted as part of registration and product listing under section 905 of the act?

### 1. Registration

Section 905(b) of the act sets forth the requirements for submission of registration information. As required by the statute, any person engaged in the manufacturing of tobacco products must register with FDA and submit the following information:

- The name and full address of each establishment engaged in manufacturing the registrant owns or operates, as of the date of registration.
- 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.

The eSubmitter application and the paper form request additional optional information that FDA also recommends be submitted, including:

- An email address, to facilitate correspondence between registrants and FDA.
- A Data Universal Numbering System (D-U-N-S®) Number[3] or other unique identifier (codes) for the place of business of the owner, the place of business of the operator, and the location of the establishment. The business entity identifier recognized by the FDA Data Council is the D-U-N-S® Number, and providing the site-specific D-U-N-S® Number for an entity will help prevent inaccuracies in FDA's database. Dun & Bradstreet assigns and maintains a database of the D-U-N-S® Numbers, which serve as unique identifiers (codes) of business entities. Upon application, each business entity is assigned a distinct site-specific 9-digit D-U-N-S® Number. If the D-U-N-S® Number for a location has not been assigned, a business may obtain one for no cost directly from Dun & Bradstreet (*http://www.dnb.com*).

### 2. Product listing information

[3] D-U-N-S® Numbers are proprietary to and controlled by Dun & Bradstreet (D&B).

Section 905(i) of the act sets forth the requirements for submitting product listing information. The act requires that, at the time of registration, the registrant submit a list of all tobacco products which are being manufactured by the registrant for commercial distribution.

The product listing must include certain accompanying information, which will vary depending on the circumstances. These are as follows:

a. If a tobacco product standard has been established under section 907 of the act (21 U.S.C. 387g) with respect to the tobacco product or the tobacco product is subject to premarket review under section 910 of the act (21 U.S.C. 387j), then the product listing must include a reference to the authority for the marketing of the tobacco product and all labeling for that product. We interpret this to mean that labeling is to be submitted as an exact, legible, full color copy.

b. Under section 905(i)(1)(B), the product listing for all other tobacco products must include all labeling for that product. It must also include "a representative sampling of advertisements" for the product. If requested by FDA for good cause, a copy of all advertisements for a particular tobacco product must be submitted. We interpret "a representative sampling of advertisements" to mean typical advertising material (excluding labeling) that reflects the full range of promotional statements made for the tobacco product. For example, if more than one magazine advertisement is used but the promotional content is essentially identical, only one need be submitted. In addition, the product listing must include "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.

If a registrant has determined that a product in its product listing is not subject to a tobacco product standard established under section 907 of the act, FDA may request that the registrant provide a brief statement of the basis for that determination.

We are interpreting section 905(i) of the act to require that each product included in a product listing be clearly identified and distinguished. Products that differ in any way, other than packaging differences that do not affect characteristics of the product, are considered to be distinct tobacco products. For example, if a soft pack and a hard pack of cigarettes have different moisture content, shelf life, or ingredient composition (including ingredients introduced in packaging but known or reasonably expected to become incorporated into the consumed product), they are to be reported as distinct products for purposes of section 905(i).

Each product is to be clearly and uniquely identified by the product category (e.g., cigarette, smokeless tobacco, paper, filter) and unique name (i.e., brand/sub-brand or other commercial name used in commercial distribution). Tobacco products are to be identified in this way because such names are needed to determine whether products in commercial distribution are listed as required. You are to include product identification numbers (e.g., SKU, catalog number, UPC) as needed to uniquely identify the product.

Section 905(i)(3) of the act sets forth requirements for submitting changes to the product list. If you introduce a tobacco product into commercial distribution for the first time, you must submit complete product listing as described above. If you discontinue the manufacture and commercial distribution of a listed product, you must submit a report of such discontinuance containing the name of the product as previously listed and the date of such discontinuance. If you resume the manufacture and commercial distribution of a previously discontinued tobacco product, you must submit a report of such resumption containing, the date of such resumption, and complete product listing information as described above.

**D. How do you submit registration and product listing information?**

The FDA eSubmitter tool is an electronic application designed to streamline the data entry process for registration and product listing at the Center for Tobacco Products (CTP). This tool provides an automatic acknowledgement of FDA receipt, and allows users to import large quantities of structured data and attach files (e.g., PDF documents and certain media files). The FDA eSubmitter tool can also streamline the process for submitting updated registration and product listing information required by sections 905(d) and 905(i)(3) of the act.

While electronic submission is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data submission and management. FDA Form 3741, an alternative tool for paper submissions, is available at www.fda.gov/tobacco.

Users of the eSubmitter tool first download and install the computer application, enter all data, and then upload the completed data through the FDA Electronic Submissions Gateway (ESG). The FDA ESG system requires users to apply for a free account before submitting data, a process which can take one to three weeks. FDA therefore urges registrants to apply for ESG accounts well in advance of the statutory deadline for data submission. Technical assistance will be available to users experiencing difficulty with any aspect of the eSubmitter tool or the ESG account. The eSubmitter tool is available at http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

**E. When must you register and list under section 905 of the act?**

Section 905(b) of the act requires registration information to be submitted by December 31, 2009, and to be resubmitted annually on or before December 31st of each year.

FDA does not intend to enforce the requirement to submit registration and product listing information under section 905 of the act by December 31, 2009, provided that the submission is received by FDA on or before February 28, 2010. We recognize that the forms developed by FDA are new to industry, and so may require additional time to complete accurately. We also recognize that electronic submission, which is strongly encouraged by FDA to improve data quality and consistency, requires several additional steps, such as obtaining an ESG account and becoming familiar with the eSubmitter electronic tool. FDA therefore believes that this additional time for the first submission of this registration and product listing information should result in submission of higher quality information.

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(i)(1) of the act requires the complete product list information to be submitted at the time of first registration. In addition, section 905(i)(3) of the act requires that certain changes in the product list be submitted biannually.

FDA intends to make the eSubmitter system available to owners and operators for submitting registration and product listing information under section 905 of the act in November 2009.

Registrants who wish to obtain a new D-U-N-S® Number should obtain one well in advance of FDA's deadline since the processing time involved in receiving a D-U-N-S® Number may take at least 30 days. Please note that the D-U-N-S® Number is not required. Alternatively, you may elect to receive a D-U-N-S® Number within one business day by paying a fee. Please consult Dun & Bradstreet (*http://www.dnb.com*) directly for more information.

# IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 3.75 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is [insert OMB control number] (expires [insert expiration date]).