



Template Name: Tobacco Registration and Product Listing  
File Name: TOBACCO\_INTRO\_905.xml

Version: 1.0  
Last Modified: 11/03/2009 02:45:47 PM

Outline

- Introduction
- Overview
- Instructions
- Identification
- Submission Content

Screen: Overview

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

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) by, among other things, adding a new chapter granting 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. To view the Tobacco Control Act, see [Public Law citation \(Pub. Law 111-31\)](#).

Complete the following question and answer form to register your establishment and submit your product listing to FDA's Center for Tobacco Products via the FDA Electronic Submissions Gateway (ESG). To register with the FDA ESG, go to [www.fda.gov/esg/](http://www.fda.gov/esg/).

For your reference, see the [Draft Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments](#).

Please note, there are several icons within the application to help guide you. Most importantly, the yellow light bulbs indicate additional instructions, definitions from the guidance document, and other helpful hints.

>Placeholder for OMB number

**Blue dots indicate required fields.**



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Screen: Instructions

## Introduction > Registration > Product Listing > Confirmation

You are in the **Introduction** section. This section includes the requirements for registration and product listing. In this next section you will be asked to identify your role and type of submission (new or update to previous submission).

Based on your answers to this section, the application will tailor subsequent questions to ensure that you only answer those questions relevant to you.



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Screen: Identification

## Statutory Requirements

Owners and Operators must register establishments and list products as required by Section 905 of the Tobacco Control Act. For information regarding the 905 requirements, please refer to the [Draft Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments](#).

**Please identify the role of the registrant. Please note that the registrant can serve multiple roles. You must indicate which roles do and do not apply to you.**

Are you an Owner?  Yes  No

Are you an Operator?  Yes  No

**In order to reduce redundant submissions, FDA strongly encourages that owners register and submit product listing information for themselves and on behalf of their operators.**

Are you registering on behalf of another party (e.g., Owner registering on behalf of an Operator or Operator registering on behalf of an Owner)?  Yes  No



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Select the appropriate submission status:

New Submission  
 Update to a Previous Submission

Enter the previous submission number provided to you by the FDA.

This update is to:

Establishment Registration  
 Product Listing



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- Owner Information
  - Establishment Registration
- Operator and Establishment Information

Screen: Instructions

## Introduction > **Registration** > Product Listing > Confirmation

You are now in the **Registration** section. This section requests contact and address information, as well as the business structure of the owner and/or operator. In addition, you will be asked to provide address information for each establishment being registered.



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  - Owner Information**
  - Establishment Registration
  - Operator and Establishment Information

Screen: Owner Information

Enter the Owner point of contact information followed by the Owner's name and address.

Title (Mr., Ms., Dr.):	<input type="text"/>
First/Given Name:	<input type="text"/>
Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>
Position Title:	<input type="text"/>
Email Address:	<input type="text"/>

Owner Name (i.e., Company or Individual Owner Name):	<input type="text"/>
Country:	<input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below) <input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State, Province, or Territory:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>
Telephone number:	( ) - - Ext.
Fax number:	( ) - -
D&B D-U-N-S Number:	<input type="text"/>

If the Owner does business by any other name, please list all such names:

Select the type of business structure (of the Owner):

For a corporation, enter the name of each corporate officer and director by clicking on the add (+) button below.

<input type="button" value="+"/> <input type="button" value="edit"/> <input type="button" value="delete"/> <input type="button" value="up"/> <input type="button" value="down"/>	0 of 50 items in the list

▶ In the case of a corporation, select the state of incorporation:	<input type="text" value="Other..."/>
▶ Please describe further:	<input type="text"/>



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Screen: Establishment Registration

Buttons: Add, Delete, Delete All, List, Detail, Info, Up, Down

Click **"Add"** to enter contact and address information for an Establishment.

To see these instructions again, you may click on the **"Info"** above.



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Screen: Establishment Registration

Buttons: Add, Delete, Delete All, List, Detail, Info, Up, Down

Item: 1 Establishment Registration Details

Enter the name and address of the Establishment.

Establishment Name:	<input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>
Telephone number:	<input type="text"/> ( ) - - Ext: <input type="text"/>
Fax number:	<input type="text"/> ( ) - -
D&B D-U-N-S Number:	<input type="text"/>

Select the operation(s) performed by your establishment:

- 4 of 10 items in the list
- Testing
  - Reconstituting Tobacco
  - Manufacturing
  - Blending
- If Other, please describe:





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Screen: Operator and Establishment Information

Buttons: Add, Delete, Delete All, List, Detail, Info, Up, Down

**How to Register your Operator(s) and Establishment(s):**

1. To begin, click **"Add"** to enter information about an Operator.
2. Enter the Operator's business structure and name and address.
3. Next, you will enter the associated Establishment name, address and functions performed.
4. To add another Operator and/or Establishment, click **"Add"** and provide the necessary information. If you do not need to list another Operator and/or Establishment, you may choose to "Continue to the Next Section".

To see these instructions again, you may click on the **"Info"** above.



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Screen: Operator and Establishment Information

Item: 1 Operator and Establishment Information Details

Is the Operator also the Owner (therefore all contact and business structure information is the same)?

Operator Information

Enter the Name and Address of the Operator:

Operator Name (i.e., Company or Individual Operator Name):

Address - Line 1:

Address - Line 2:

City:

State:

Post Office or Zip Code:

D&B D-U-N-S Number:

If the Operator does business by any other name, please list all such names:

Select the type of business structure (of the Operator):

For a corporation, enter the name of each corporate officer and director by clicking on the add (+) button below.

0 of 50 items in the list

- In the case of a Corporation, select the state of incorporation:
- Please describe further:

Establishment Information

Is the Operator Name and Address the same as the Establishment Name and Address?

Enter the name and address of the Establishment:

Establishment Name (i.e., Company or Individual Establishment Name):

Address - Line 1:

Address - Line 2:

City:

State:

Post Office or Zip Code:

Telephone number:  ( ) - - - Ext:

Fax number:  ( ) - - -

D&B D-U-N-S Number:

Select the operation(s) performed by the Establishment:

0 of 30 items in the list

- If Other, please describe:



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Screen: Instructions

Introduction > Registration > **Product Listing** > Confirmation

You are now in the **Product Listing** section. This section is used to enter information about your product(s), including advertising, labeling and consumer information.



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Screen: Product Identification

Buttons: Add, Delete, Delete All, List, Detail, Info, Up, Down

**How to List Your Product(s):**

1. To begin, click **"Add"** to enter information about a product.
2. Next, you will enter the advertising and labeling information for a particular product before entering another product.
3. Once you have entered the advertising and labeling information for a product, click "Add" to list another product. If you do not need to list another product, you can choose to "Continue to the Next Section".

To see these instructions again, you may click on the **"Info"** above.



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Screen: Product Identification

Buttons: Add, Delete, Delete All, List, Detail, Info

Item: 1 Product Details

**Product Information**

Enter the product name (i.e. brand/sub-brand or other commercial name used in commercial distribution):

A product identification number must be provided if needed to uniquely identify the product:

Select the type of product identification number:

Select the intended use of the product:

Select the product category:

If Other, please describe:

Select the flavor:

If Other, please describe:

**Labeling**

Attach all labeling for this product by clicking on the plus sign. For each item of labeling, we request that you provide the following information in the description section:

- Type of labeling material (e.g., package labeling)
- Internal identification number, as applicable
- UPC code, as applicable
- Date labeling was first disseminated

0 items in the list

Title	Name	Date	Size	Pat
-------	------	------	------	-----

**Consumer Information**

Consumer information may be required. Please see the guidance document, section III.C.2, for additional details. Please attach your consumer information by clicking on the plus sign. For each item, we request that you provide the following information in the "Description of File" section when selecting your file:

- Type of material (e.g., consumer brochure)
- Internal identification number, as applicable
- Date material was first disseminated

0 items in the list

Title	Name	Date	Size	Pat
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**Advertising**

A representative sampling of advertising may be required. Please see the guidance document, section III.C.2, for additional details. Please attach your advertisements by clicking on the plus sign. For each advertisement, we request that you provide the following information in the "Description of File" section when selecting your file:

- Type of advertising material (e.g., magazine)
- Internal identification number, as applicable
- Date advertisement was first disseminated

0 items in the list

Title	Name	Date	Size	Pat
-------	------	------	------	-----



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- Instructions
- Confirmation Statement
- Package Files for Submission

Screen: Instructions

**Introduction > Registration > Product Listing > Confirmation**

You are now in the **Confirmation** section. This section contains a confirmation statement, and requests additional contact and address information, as needed. Your last step in this section is to package your submission for transmission to the Center for Tobacco Products.

The packaging process will validate that you have completed data entry.



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Screen: Confirmation Statement

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate. I agree to report changes to this information as required under Section 905 of the Act.  Agree

Identify the person submitting this form:

Authorized Agent

If authorized Agent, enter your name and address.

Title (Mr., Ms., Dr.):	<input type="text"/>
First/Given Name:	<input type="text"/>
Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>
Position Title:	<input type="text"/>
Email Address:	<input type="text"/>

Company Name:	<input type="text"/>
Country:	<input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below) <input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State, Province, or Territory:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>

Telephone number:	<input type="text"/> ( ) - - Ext: <input type="text"/>
Fax number:	<input type="text"/> ( ) - -



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**Screen: Package Files for Submission**

**STOP** You have reached the end of this submission. You may now package the submission and transmit it to CTP via the ESG or on CD-ROM in order to fulfill your statutory requirements.

At this time, you may save and close this submission to return to it at a later time. To do so, simply click Save and then Close from the File Menu or top Tool Bar. To re-open this submission after closing, select Open Existing Submission from the Intro Screen or Open from the File Menu.

If you would like to package this submission at this time in preparation for transmitting to FDA, please begin the packaging process by selecting Output > Package Files for Submission or by clicking the Package icon from the top toolbar. If any required data is missing, the packaging process will not begin and a Missing Data Report will be displayed. Please ensure that all required questions are completed and all applicable documents have been attached within the submission. Specific directions for packaging your submission can be found in the eSubmitter User Manual and/or Quick Guide.

If you would like to prepare another submission to fulfill other FDA requirements, please select "New" from the File Menu to begin compiling a new submission and be sure to select the appropriate submission type.