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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 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/.

For your reference, see the 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.

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 0910-0650 (expires 5/31/2010).

Blue dots indicate required fields.

OMB No: 0910-0650, Expiration Date: 5/31/2010

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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.

Instructions and helpdesk assistance (esubmitter@fda.hhs.gov or 1-877-FDA-1CTP (1-877-332-1287)) are available to help you create your eSubmitter submissions for the Center for Tobacco Products.

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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 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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Screen: Submission Content

Submission Status

The following submission options are available:

New Registration and Product Listing should be used when you first register establishments and list products with FDA.

Update to a Registration should be used if you are completing your annual registration with the FDA (post the initial registration and product listing) or if you are opening a new establishment, or closing an establishment that is already registered with the FDA.

Update to Product List should be used if you are completing your bi-annual update to your product list (post the initial registration and product listing) (per section 905(i)(3)).

When submitting an update, provide a complete registration or product list as this submission will serve as FDA's most recent information on record. You may re-use your initial submission file as a starting point by selecting File > Save As. The data from the old submission will be copied over to the new submission with the new file name. If you are unsure how to submit an update, please contact the help desk at eSubmitter@fda.hhs.gov or by telephone at 1-877-FDA-1CTP.

Please note: If you are discontinuing or resuming a discontinued product per 905(i)(3), you are required to submit a bi-annual update to product list through only 905 and not 904(a)(1).

For information regarding the section 905 requirements, please refer to the Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.

Select the appropriate submission status:

- ○ New Registration and Product Listing (per 905(b) and 905(i)(1))
- ◉ Update to a Registration (per 905(b)) (previously submitted to the FDA)
- ○ Update to a Product List (per 905(i)(3)) (previously submitted to the FDA)

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Registration | Confirmation | Introduction | Summary

Update Summary

Screen: Update Summary

Enter a brief summary of the updates to be provided in this submission.

Provide the status of your current address information. All address information submitted to FDA should be current at the time of registration. If any address information has changed since you previously submitted registration information to FDA, the old and new address should be included in this submission. If you are only adding/deleting an establishment and not changing a previously submitted address, please select no change of address to report.

Note: The person who submits the Update to Registration must be the same person who submitted the annual registration.

- No Change of Address to Report
- Reporting a Change of Address

Identify from the following role(s) if you would like to change a previously submitted address(es).

- Address of the Owner
- Address of an Operator

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Outline

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- Instructions
- Owner Information
  - Establishment Registration
- Operator and Establishment Registrat

Screen: Owner Information

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

Contact

Title (Mr., Ms., Dr.):	
First/Given Name:	
Middle Name:	
Last Name:	
Position Title:	
Email Address:	

Address

Owner Name (i.e., Company or Individual Owner Name):	
Country:	◉ United States of America ○ Other (select below)
Address - Line 1:	
Address - Line 2:	
City:	
State, Province, or Territory:	
Post Office or Zip Code:	____-____

Phone Numbers

Telephone number:	(___) ___-____ Ext: ____
Fax number:	(___) ___-____

Reference Numbers (for the Owner Name (i.e., Company or Individual Owner Name) specified above)

FDA Establishment Identifier (FEI):	
D&B D-U-N-S Number:	

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.

0 of 50 items in the list

In the case of a corporation, select the state of incorporation:

Please describe further:

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

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Outline

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

Screen: Operator and Establishment Registration

Add | Delete | Delete All | List | Detail | Info

How to Register your Operator(s) and Establishment(s):
You may enter data directly into this screen using the data entry method. As an alternative to data entry, you may enter this information into a pre-formatted spreadsheet that CTP has specifically designed to be imported here. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the **"Add"** button 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 on the **"Add"** button again.

Import Method:

1. Click on the link (Import Spreadsheet Template for Operator and Establishment Registration Updates) to launch the pre-formatted Excel spreadsheet.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information. You will need to navigate to the location of the file during the import process.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner of this screen next to the yellow light bulb and follow the import wizard.
5. After all data is imported, you can click on the **"List"** button to view and verify the imported product(s) information.

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

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Outline

Introduction | Summary
Registration | Confirmation

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

Screen: Operator and Establishment Registration

Add | Delete | Delete All | List | Detail | Info

Item: 1 **Operator and Establishment Information Details**

Please note that there are new questions requesting updated information below.

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

Contact

Title (Mr., Ms., Dr.):	
First/Given Name:	
Middle Name:	
Last Name:	
Position Title:	
Email Address:	

Address

Operator Name (i.e., Company or Individual Operator Name): Address - Line 1:	
Address - Line 2:	
City:	
State:	
Post Office or Zip Code:	____-____

Phone Numbers

Telephone number:	(___) ___-____ Ext: ____
Fax number:	(___) ___-____

Reference Numbers (for the Operator Name (i.e., Company or Individual Operator Name) specified above)

FDA Establishment Identifier (FEI):	
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 (1 required)

In the case of a Corporation, select the state of incorporation:

Please describe further:

Establishment Information

Select the status of the establishment.	No Change
Provide the date the establishment was opened or closed:	__/__/____

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

Enter the name and address of the Establishment.

Contact

Title (Mr., Ms., Dr.):

First/Given Name:

Middle Name:

Last Name:

Position Title:

Email Address:

Address

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

Address - Line 1:

Address - Line 2:

City:

State:

Post Office or Zip Code: ____-____

Phone Numbers

Telephone number: (___) ___-____ Ext: ____

Fax number: (___) ___-____

Reference Numbers (for the Establishment Name (i.e., Company or Individual Establishment Name) specified above)

FDA Establishment Identifier (FEI):

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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Registration | Confirmation

- Instructions
- Confirmation Statement
- Package Files for Submission

Screen: Instructions

Introduction > Registration > **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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- Confirmation Statement
- Package Files for Submission

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.

Identify the person submitting this form:

If authorized Agent, enter your name and address.

Title (Mr., Ms., Dr.):	
First/Given Name:	
Middle Name:	
Last Name:	
Position Title:	
Email Address:	
Company Name:	
Country:	United States of America / Other (select below)
Address - Line 1:	
Address - Line 2:	
City:	
State, Province, or Territory:	
Post Office or Zip Code:	
Telephone number:	( ) - Ext:
Fax number:	( ) -

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Outline

Introduction | Summary
Registration | Confirmation

- Instructions
- Confirmation Statement
- Package Files for Submission

Screen: Package Files for Submission

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 requirements. Submission via the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

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