

CeSub eDesigner

File Edit View Designer Output Tools Help

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/essg/.

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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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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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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Screen: Instructions
 Introduction > **Submitter Identification** > Product Listing > Confirmation
 You are in the **Submitter Identification** section. This section requests relevant contact and address information.

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Screen: Submitter Identification
 Please provide the submitter contact and address information below:

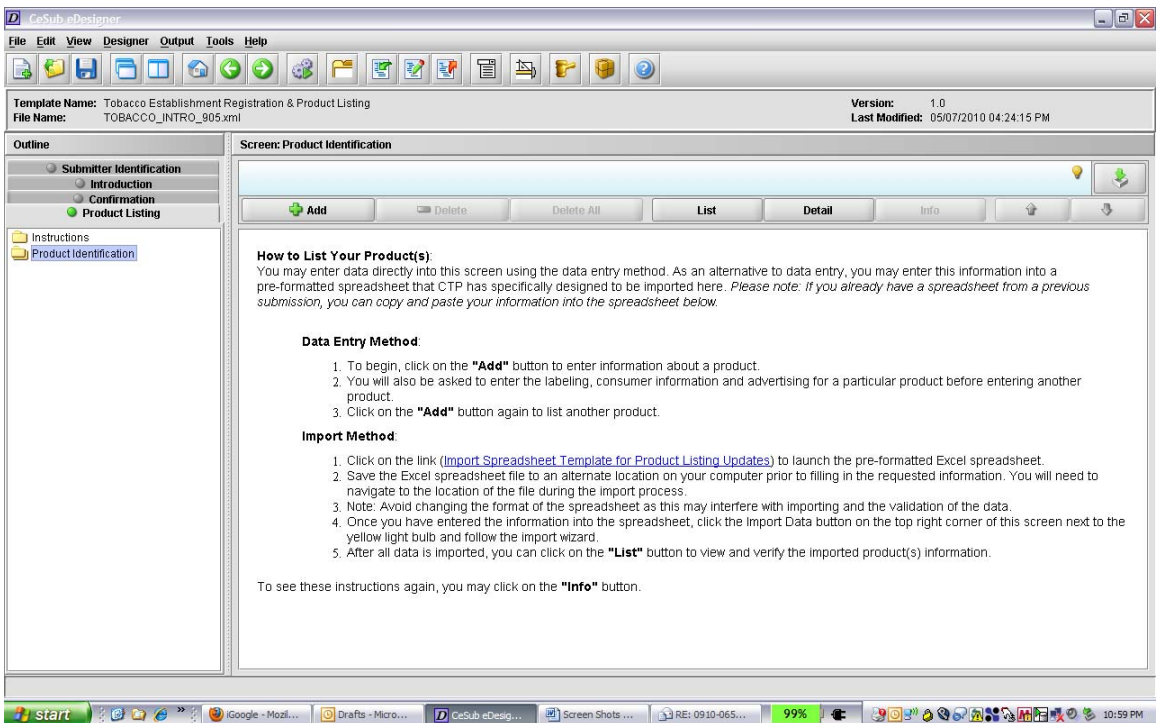
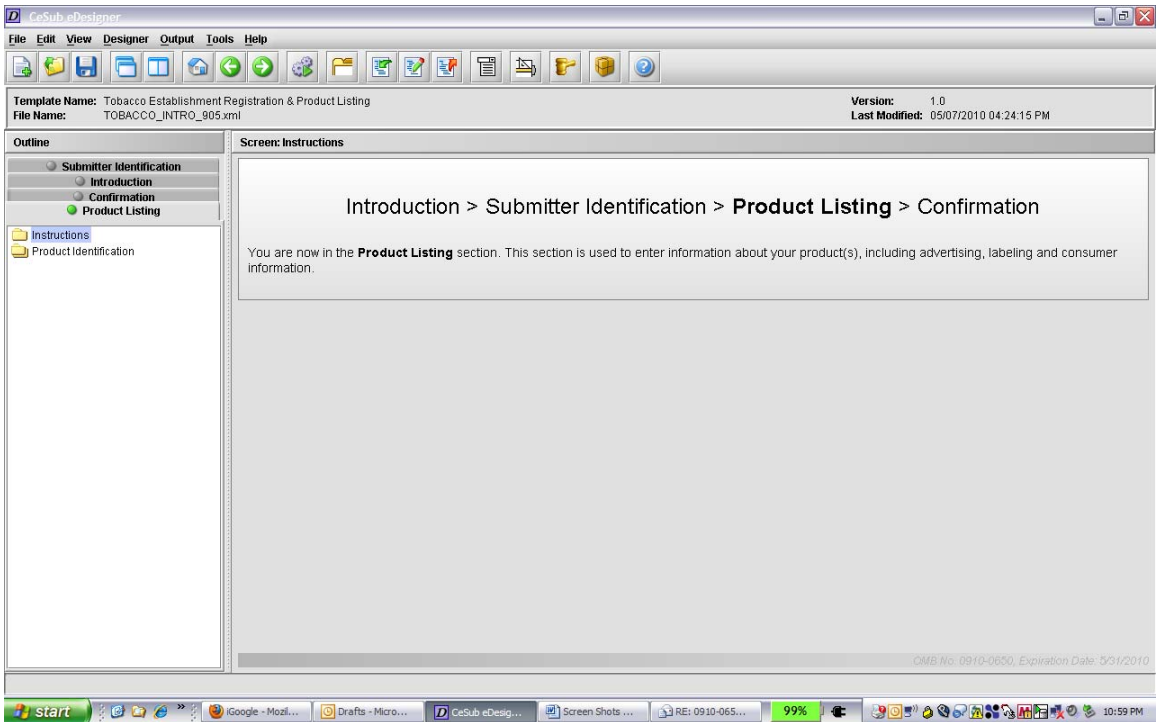
Contact
 Title (Mr., Ms., Dr.):
 First/Given Name:
 Middle Name:
 Last Name:
 Position Title:
 Email Address:

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:

Phone Numbers
 Telephone number: () - - Ext.
 Fax number: () - -

Reference Numbers (for the Company Name specified above)
 FDA Establishment Identifier (FEI):
 D&B D-U-N-S Number:

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Item: 1 Product Details

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

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:

If known, enter the FDA-assigned tracking number (e.g., TP#####) for your tobacco product:

If your product has been introduced to market, discontinued or reintroduced since your last product listing, indicate the most recent change:

Provide the appropriate date:

Select use of this product:

Select the product category:

If Other, please describe further:

Select the flavor:

If Other, please describe:

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 optional 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	Path

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 optional 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	Path

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 optional 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	Path

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