

How to Create Your eSubmitter Submissions for the Center for Tobacco Products

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Center for Tobacco Products eSubmitter [Overview](#)

The Center for Tobacco Products eSubmitter application was designed to assist industry with the electronic submission of registration and product listing, ingredient listing and health data information. These instructions are intended to address technical aspects of completing your electronic submission.

Users may electronically submit the following information through the eSubmitter application:

- Tobacco Establishment Registration, per section 905(b) of the Federal Food, Drug and Cosmetic Act (the act).
- Tobacco Product Listing, per sections 905(i)(1) and 905(i)(3) of the act.
- Tobacco Product Ingredient Submission, per sections 904(a)(1) and 904(c) of the act.
- Tobacco Product Data Collection, per section 904(a)(4) of the act.

These instructions are meant to accompany but not to substitute for any published guidance documents on these topics. Published guidance documents include:

- [Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.](#)

Submission Checklist

To electronically submit information using eSubmitter, users should use the checklist below to facilitate timely and complete submissions:

1. Did you compile your submission using the eSubmitter software?

- Download the eSubmitter tool at:
<http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>
- For help with the compilation of your submission, refer to the eSubmitter [Quick Guide](#) and the full-length eSubmitter [User Manual](#).
- For technical support using eSubmitter, contact eSubmitter@fda.hhs.gov.
- For questions regarding the Draft Guidance or the Tobacco Act, contact <http://www.regulations.gov>.

2. Did you obtain and setup your Electronic Submission Gateway Account?

The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) enables secure submission of information to the Center for Tobacco Products. The ESG is used across FDA as a tool for accepting electronic regulatory submissions.

If you are submitting your Registration and Product Listing, Ingredients Listing and Health Data submission electronically, you are encouraged to submit through the ESG. To obtain an ESG account, see the following checklist:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

For policy questions and to request a WebTrader account, contact esgprep@fda.hhs.gov.

For assistance with the registration or testing process, contact esgreg@gnsi.com.

3. Did you obtain a Dun & Bradstreet Data Universal Numbering System (D-U-N-S®) Number for each establishment being registered?

The D-U-N-S® Number is recommended, but not required for electronic submission of registration information. For more information, see below.

4. Did you create a self-signed digital signature for use in eSubmitter?

To package your eSubmitter submissions, you must create a personal self-signed digital signature. For help with digital signatures in Adobe Acrobat, refer to the "Creating Digital Signatures Quick Guide" and "eSubmitter Quick Guide: Packaging with Digital Signature" documents located within the "Manual" folder in the eSubmitter directory.

5. Did you package the submission using the eSubmitter software, generating a submission .ZIP file?

For help with packaging your submission, refer to the eSubmitter Quick Guide.

How to [Obtain a D-U-N-S® Number](#)

A Data Universal Numbering System (D-U-N-S®) Number is a unique nine-digit sequence provided by Dun & Bradstreet. The D-U-N-S® Number is site specific. Therefore, each distinct physical location of an entity (such as branches, divisions, and headquarters) may be assigned a D-U-N-S® Number. The site-specific D-U-N-S® Number is a widely recognized business identification tool, and serves as a useful resource for FDA in identifying and verifying certain business information submitted by a user. It is recommended, but not required, for submission of information to FDA.

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. You may obtain a new number, or verify an existing number, by phone or online. A new D-U-N-S® Number requires approximately 30 business days to be processed, and is assigned by email. A business may receive a D-U-N-S® Number in approximately 10 business days for an expedited service fee of \$14.95 per D-U-N-S® Number. Please note that a business entity may not request or apply for a new D-U-N-S® Number on behalf of another business entity due to the verification procedures used by Dun & Bradstreet.


More information is available at www.dnb.com.

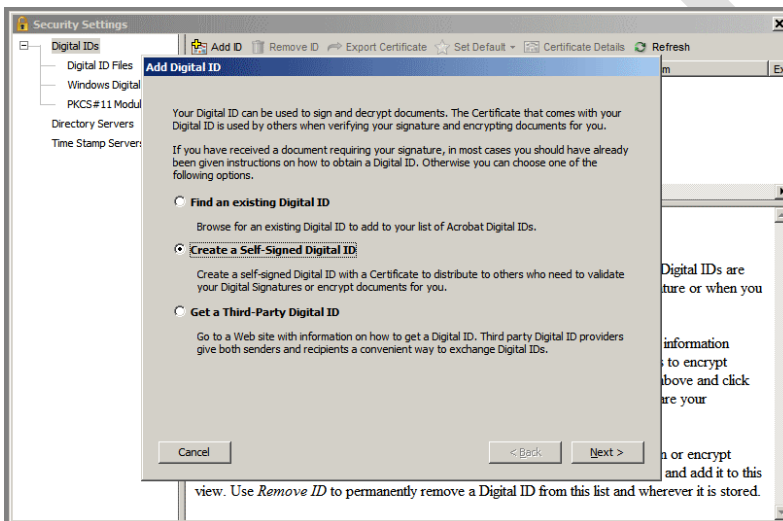
Step-by-step instructions to obtain a D-U-N-S® Number for businesses based either in the United States or abroad are available at:
http://www.dnb.gov/federal_compliance/fda/DUNSrequest/requestGuide.html.

How to Create a Digital Signature

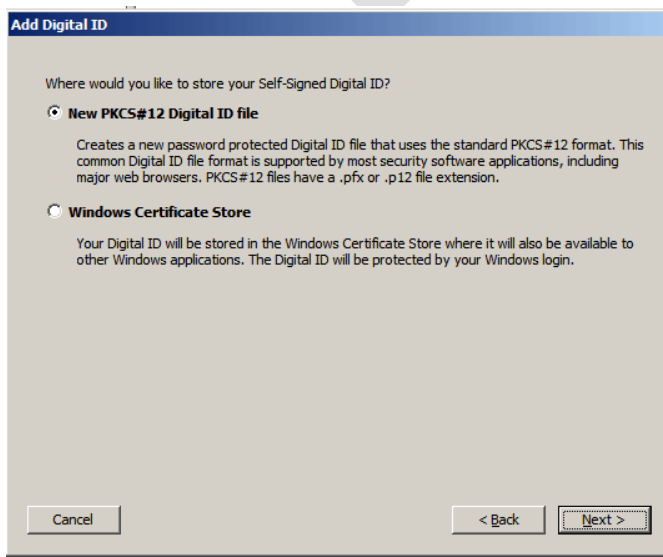
The eSubmitter software allows users to digitally sign their submissions. To use this feature, you must create a digital signature to identify yourself. Follow the instructions below to create a digital signature in either Adobe Reader and Adobe Acrobat Professional, and to import your new digital signature into eSubmitter.

Create a Digital ID

1. Access the **Security Settings** dialog:
 - **Adobe Reader** - Click **Document > Security Settings**.
 - **Adobe Pro** - Click **Advanced > Security Settings**.
2. Click on the  button to display the **Add Digital Id** dialog.
3. Select the **Create a Self-Signed Digital ID** radio button and click **Next >**



4. Read the message that is displayed and click **Next >**



Click the storage location of your Digital ID. Click the **Next >** button and click **Next >**

6. Add your information in the text fields provided and click **Next >**

Add Digital ID

Enter your Identity information to be used when generating the Self-Signed Certificate.

Name (e.g. John Smith):

Organizational Unit:

Organization Name:

Email Address:

Country/Region:

Enable Unicode Support

Key Algorithm:

Use Digital ID for:

Note: The values you enter for your *email address* and *organization name* will be used to validate your signature against FDA records. You will need to supply information for the first five fields only. Be sure to enter the location where you would like your digital id saved, and a password. Confirm the password and click **Finish**. the remaining two fields and check the **Enable Unicode Support** box

Add Digital ID

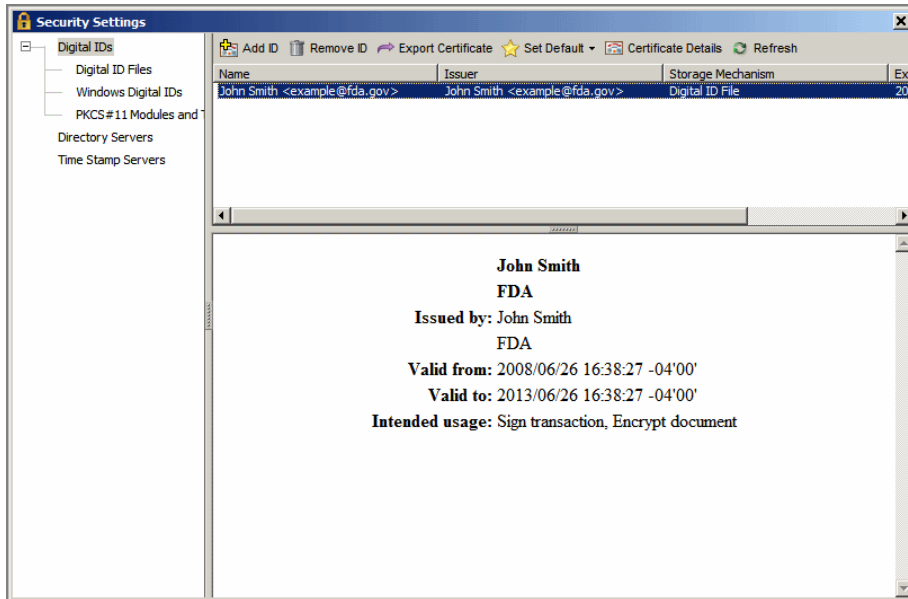
Enter a file location and password for your new Digital ID file. You will need the password when you use the Digital ID to sign or decrypt documents. You should make a note of the file location so that you can copy this file for backup or other purposes. You can later change options for this file by going to the menu Advanced > Security Settings.

File Name:

Password:

Confirm Password:

8. In the **Security Settings** dialog, click on the newly created digital id in the upper right-hand pane to view the summary of the id. The summary is shown in the lower right-hand pane.



How to [Import Tobacco Product Information](#) using Excel

To submit product information via eSubmitter, each industry user is able to complete the following steps to import pre-populated data to ensure accurate and timely submission. Screens in eSubmitter that are capable of imports will contain the “import data” icon in the upper right quadrant of the page. There are current four (4) screens relating to your Tobacco product that allow data import.

Screen 1: Operator and Establishment Information (905)

Screen View **Registration: Operator and Establishment Information**

Add **Delete** **Delete All** **List** **Detail** **Info**

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.

Outline View

Screen 2: Brand/Sub-Brand Information (905)

Screen View **Product Listing: Brand/Sub-Brand Information**

Add **Delete** **Delete All** **List** **Detail** **Info**

How to List Your Product(s):

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

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

Outline View

Screen 3: Product Identification (904)

Screen View Introduction: Product Identification

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

Instructions:

1. To begin, click **"Add"** to enter your Brands/Sub-Brands.
2. Next, you will enter the detailed ingredient information for each Brand/Sub-Brand.
3. Once you have entered the ingredient information for a Brand/Sub-Brand, you will be prompted to "Add another Brand/Sub-Brand", which will return you to this screen. If you do not need to list another Brand/Sub-Brand, you can choose to "Continue to the Next Section".

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

Navigation: Previous, Outline View, Next

Screen 4: Ingredient Identification (904)

Screen View Introduction: Ingredient Identification

Brand/Sub-Brand Name No Data Provided

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

Instructions:

Please enter all ingredients for the identified product. To facilitate data entry, please enter all directly added ingredients before reaction product ingredients.

1. To begin, click **"Add"** to enter data for a particular ingredient.

Navigation: Previous, Outline View, Next

Preparing your excel spreadsheet

The Center for Tobacco Products has supplied spreadsheet templates for proper entering of data. These templates have been developed to properly import the data into the eSubmitter tool. Templates are available for each of the four screens shown above.

Within each spreadsheet you can find descriptive information about each field by scrolling over the column names.

C	D	E	F	G
Unique Identifier	Type of Identifier	Column D: Select a type of identifier for your Unique Identifier from the following options.		Quantity
Acme Nutmeg #27	OTHER	UNII - FDA UNII Code CAS - CAS Number IUPAC - IUPAC Name CATALOG # - Catalog No. UPC - UPC Code OTHER - Other Maximum length of 60		1.4
CA01442	UNII			0.0000002
				Varies
*	*		*	*

Load your data into the spreadsheet template and save it as an **.xls** file. You will be required to recall this file location during the import process. **Note:** eSubmitter is not compatible with **.xlsx** files at this time.

On each of the 904 and 905 Tobacco import screens, you can begin by clicking the **"Import data"** icon which will bring up the **"Data Import Wizard"**.



Data Import Wizard

Step 1

Overview and Import Configuration

What Importing Data Entails...

The purpose of the data import capability is to alleviate the task of manually performing data entry of large amounts of data that already exists elsewhere by allowing it to be imported automatically into the report. "Click" the hint option (i.e., lightbulb icon) for additional information on each step of the process.

During the Import process, you will identify the import source, set the import configuration, verify a sampling of the data, and perform the actual importing of the data.

Identify the Import Source

- Select the Source Type Microsoft Excel
- Display the Source Definition Display Definition Instructions...
- Select the Source File

Set the Import Configuration Options


- Is First Row Header Information?
- Set Data Integration Approach Add to Existing Data

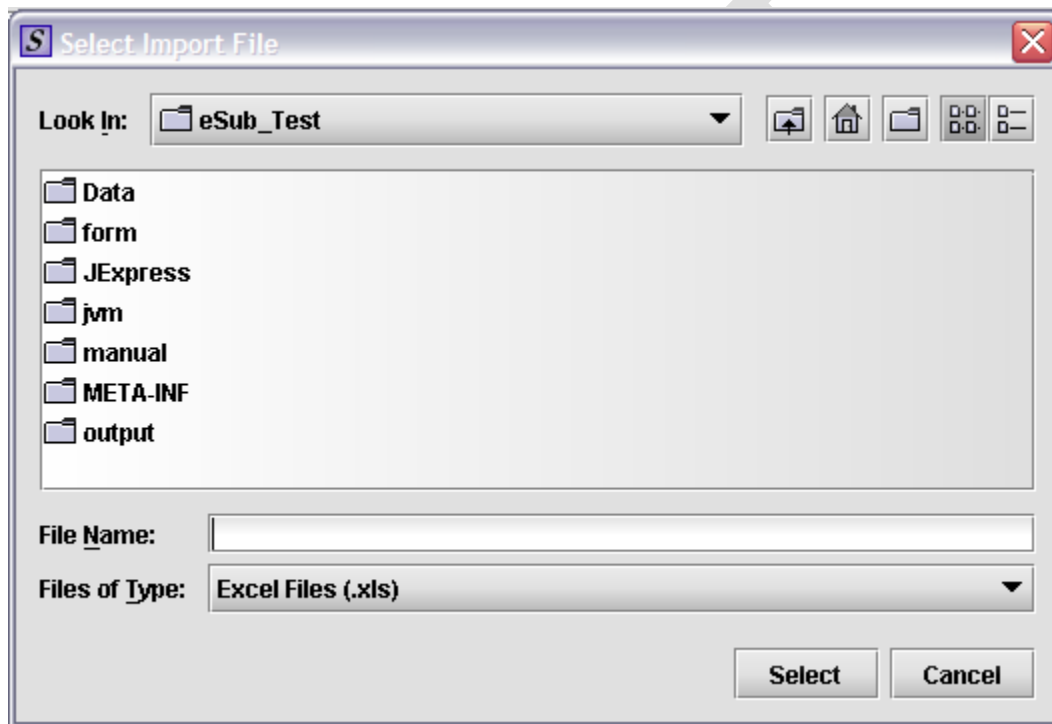
Cancel
Previous
Next
Done



The Data Import Wizard contains the following fields:

Identify the Import Source

- Select the Source Type - Only Microsoft Excel files are allowable
- Display the Source Definition - The Source Definition will assist in defining your variables and the constraints of your data. Source Definitions for each of the four (4) Tobacco screens are included in the [appendices](#).
- Select the Source File - allows the user to use an existing excel spreadsheet on their computer to pre-populate the data. There are three options aligned to the “Select the Source File” field.

- o  Select File - Select one of the four (4) Tobacco Excel spreadsheet templates provided by the Center for Tobacco Products that you have input data into



- o  View File - Preview the spreadsheet that you would like the data to be imported from
- o  Clear File - To select a different Tobacco product file or stop the process towards importing data, select the Clear File icon

Set the Import Configuration Options

- Is First Row Header Information - Always check the box to indicate that the first row of the spreadsheet contains column title information. Each of the provided Tobacco templates includes header rows that describe the type of information that needs to be entered.
- Set Data Integration Approach
 - o Add to existing data - This option allows you to add to the existing list of Tobacco Product values currently in your data set. This does not replace the values already entered.
 - o Replace existing data - This option allows you to overwrite Tobacco Product information that is in your data set and replace using the values in the imported spreadsheet.

The screenshot shows the 'Data Import Wizard' dialog box, titled 'Data Import Wizard' with a close button in the top right corner. The window has a light green header bar. Below the header, there is a tab labeled 'Step 1 Overview and Import Configuration'. The main content area is divided into three sections:

- What Importing Data Entails...**: A text box containing two paragraphs. The first paragraph states: 'The purpose of the data import capability is to alleviate the task of manually performing data entry of large amounts of data that already exists elsewhere by allowing it to be imported automatically into the report. "Click" the hint option (i.e., lightbulb icon) for additional information on each step of the process.' The second paragraph states: 'During the Import process, you will identify the import source, set the import configuration, verify a sampling of the data, and perform the actual importing of the data.'
- Identify the Import Source**: A section with a lightbulb icon in the top right. It contains three items:
 - Select the Source Type: A dropdown menu currently set to 'Microsoft Excel'.
 - Display the Source Definition: A button labeled 'Display Definition Instructions...'.
 - Select the Source File: A text input field with a file explorer icon, a search icon, and a refresh icon to its right.
- Set the Import Configuration Options**: A section with a lightbulb icon in the top right. It contains two items:
 - Is First Row Header Information?: A checkbox that is currently unchecked.
 - Set Data Integration Approach: A dropdown menu currently set to 'Add to Existing Data'.

At the bottom of the dialog, there are four buttons: 'Cancel', 'Previous', 'Next', and 'Done'. The 'Next' button is highlighted with a grey background.

Click  to import your Tobacco Product file into eSubmitter

Appendix A: Ingredient Identification Source Definition

Source Definitions: Ingredient Identification (904)

Question/Column	Constraints
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Unique Identifier	Maximum length of 60 Response required
Type of Unique Identifier	Response required An applicable code (shown before the dash) from the following list of options: UNII - FDA UNII Code CAS - CAS Number IUPAC - IUPAC Name CATALOG # - Catalog No. UPC - UPC Code OTHER – Other...
Type of Unique Identifier, If Other	Maximum length of 60 Response required
Name of Ingredient Manufacturer	Maximum length of 60
Quantity of Ingredient	Maximum length of 60 Response required
Unit of Measure	Response required An applicable code (shown before the dash) from the following list of options: g - grams mg - milligrams mcg - micrograms pg - picograms
Quantity Reported Per	An applicable code (shown before the dash) from the following list of options: GOP - gram of product UOU - unit of use
Amount Description, if Varies	Maximum length of 1000 Response required
Limit of Detection, If 0	Maximum length of 60 Response required

Question/Column	Constraints
Unit of Measure, if Limit of Detection	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>g - grams mg - milligrams mcg - micrograms pg - picograms</p>
Type/Grade/Quality	Maximum length of 100
Expected Ingredient Functions	
Expected Ingredient Functions, If Other	Maximum length of 100
Ingredient Added to Paper?	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>Y - Yes N - No</p>
Ingredient Added to Filter?	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>Y - Yes N - No</p>
Ingredient Added to Tobacco?	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>Y - Yes N - No</p>
Ingredient Added to, If Other	Maximum length of 100
Is the ingredient Tobacco?	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>Y - Yes N - No</p>

Question/Column	Constraints
Cure Method, If Tobacco	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>AIR - Air FIRE - Fire FLUE - Flue STEAM - Steam SUN - Sun OTHER - Other</p>
Cure Method to, If Other	Maximum length of 100
Genetic or Transgenic Modification	<p>Maximum length of 60 Response required</p>
Is this a Reaction Product?	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>Y - Yes N - No</p>
Reactive Ingredients, If Reaction	
Custom made to your specifications?	<p>Response required An applicable code (shown before the dash) from the following list of options:</p> <p>Y - Yes N - No</p>
Specified Ingredients, If Custom	
Specifications, If Custom	