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- For questions regarding the Draft Guidance or the Tobacco Act, contact http://www.regulations.gov.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.](mailto: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.dnbgov.com/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 [Add ID] button to display the **Add Digital Id** dialog.

3. Select the **Create a Self-Signed Digital ID** radio button and click **Next >**
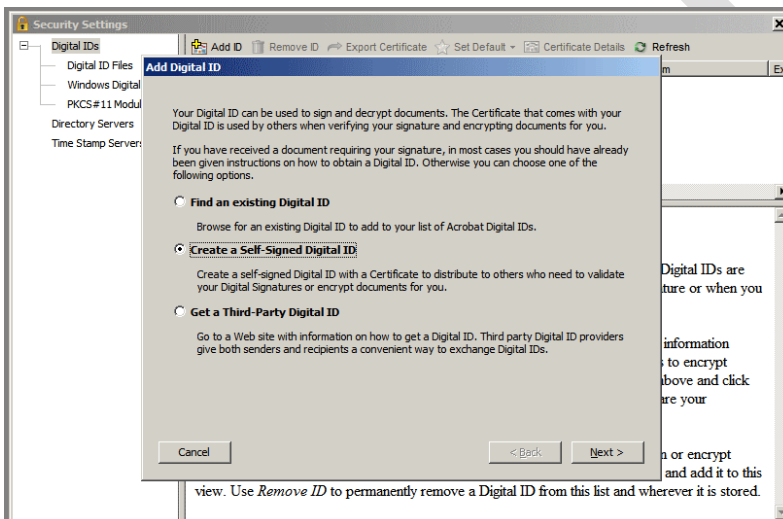
4. Read the message that is displayed and click **Next >**
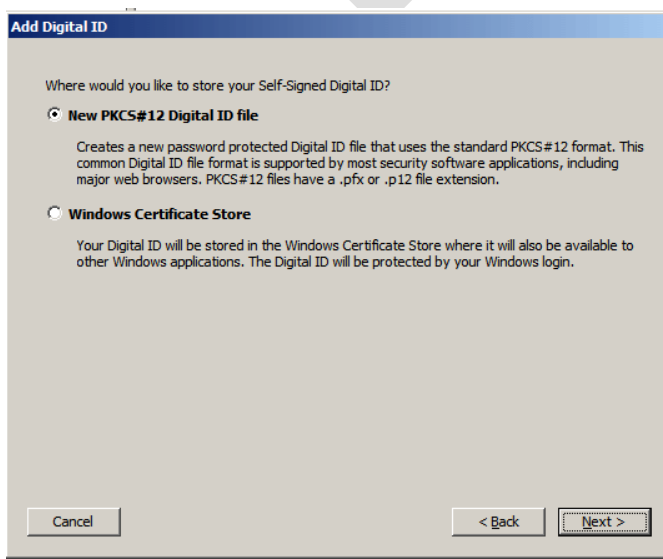
...ect the storage location of your Digital ID. ...utton and click **Next >**

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

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7. 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.

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.
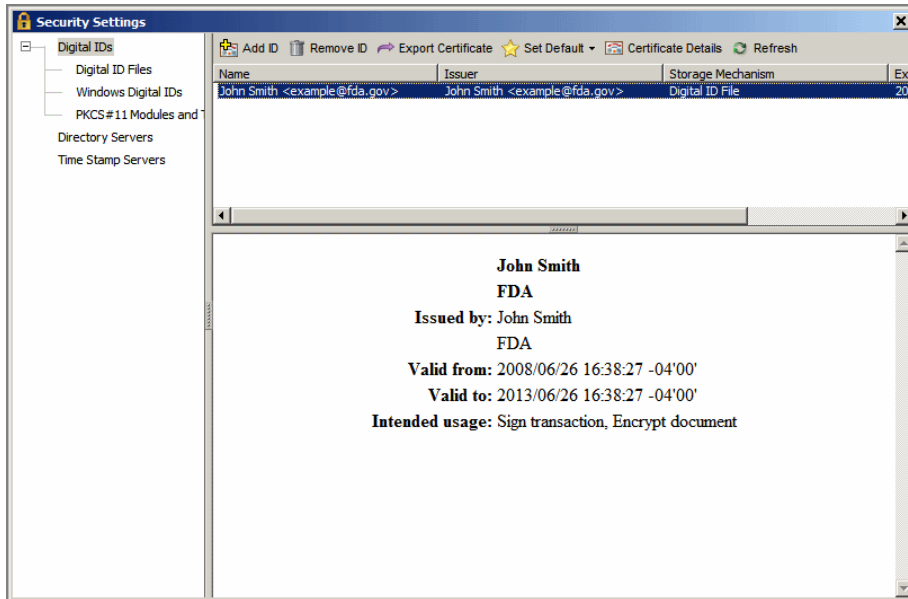
How to Import Tobacco Product Information using Excel

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 2: Brand/Sub-Brand Information (905)

Screen 3: Product Identification (904)

Screen 4: Ingredient Identification (904)

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 indentifier for your Unique Identifier from the following options.		**Quantity**
	Acme Nutmeg #27	OTHER	Na **UNII - FDA UNII Code**		1.4
	CA01442	UNII	**CAS - CAS Number**		0.0000002
			IUPAC - IUPAC Name		Varies
	*	*	* **CATALOG # - Catalog No.**		*
			UPC - UPC Code		
			OTHER - Other		
			Maximum length of 60		

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 the "**Import data**" icon which will bring up the "**Data Import Wizard**.

The Data Import Wizard contains the following fields:

Identify the Import Source

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- 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   [icon]   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   [icon]   View File – Preview the spreadsheet that you would like the data to be imported from

  - o   [icon]   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.
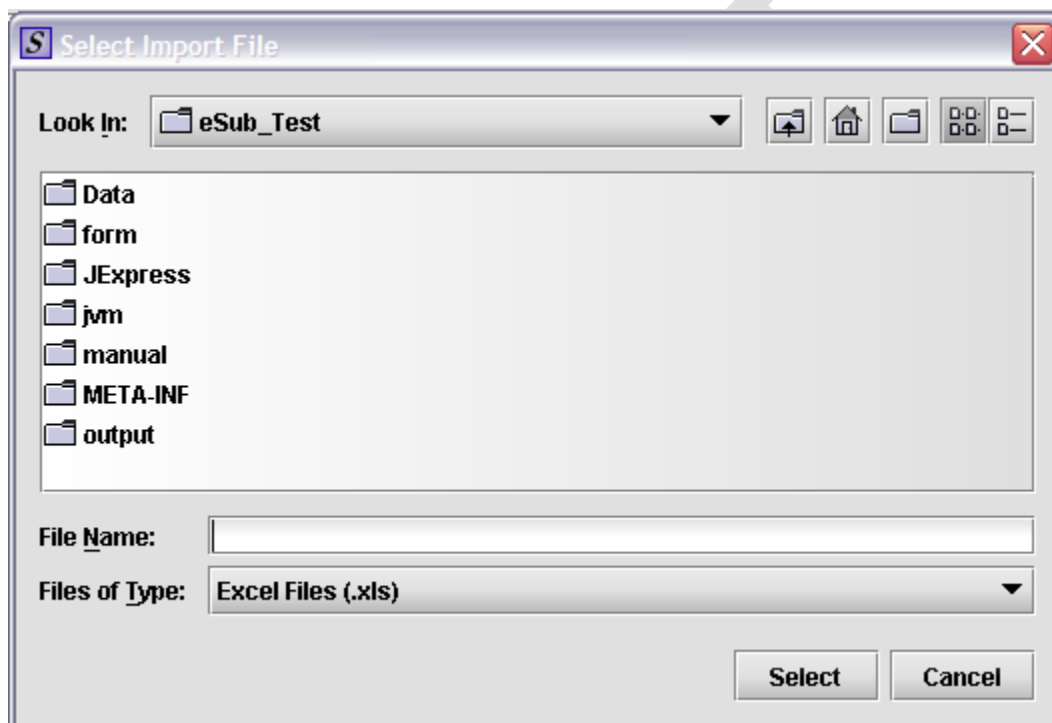- Set Data Integration Approach
  - o Add to existing data - This option allows you to add to the existing list of Tobacco Product values currently in your data set. This does not replace the values already entered.
  - o Replace existing data – This option allows you to overwrite Tobacco Product information that is in your data set and replace using the values in the imported spreadsheet.

Click [**Next**] to import your Tobacco Product file into eSubmitter

Appendix A: Ingredient Identification Source Definition

Source Definitions: Ingredient Identification (904)

Question/Column	Constraints

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	Response required
	An applicable code (shown before the dash) from the following list of options:
	
	   g - grams
	   mg - milligrams
	   mcg - micrograms
	   pg - picograms

Type/Grade/Quality	Maximum length of 100
Expected Ingredient Functions	
Expected Ingredient Functions, If Other	Maximum length of 100

Ingredient Added to Paper?	Response required
	An applicable code (shown before the dash) from the following list of options:
	
	   Y - Yes
	   N - No

Ingredient Added to Filter?	Response required
	An applicable code (shown before the dash) from the following list of options:
	
	   Y - Yes
	   N - No

Ingredient Added to Tobacco?	Response required
	An applicable code (shown before the dash) from the following list of options:
	
	   Y - Yes
	   N - No

Ingredient Added to, If Other	Maximum length of 100

Is the ingredient Tobacco?	Response required
	An applicable code (shown before the dash) from the following list of options:
	
	   Y - Yes
	   N - No

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