U.S. Food and Drug Administration

Tobacco Registration and Product Listing Module (TRLM)

User Guide

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1. Introduction

This document provides step-by-step instructions for creating and updating registrations in the Tobacco Registration and Product Listing Module (TRLM).

This guide is intended to assist owners and operators of domestic tobacco product establishments with the registration and product listing submissions required by section 905 of the Food, Drug, and Cosmetic Act (FD&C Act).

All registrants shall, at the time of registration file a list of all regulated tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain related information, including all product labeling. An owner or operator may authorize a third-party agent to register and submit product listing information on their behalf. Please refer to the [Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishment](#) guidance document for additional information.

2. Objectives

TRLM has been updated to help users see their current status of their registration process, provide users more options to add product listings, streamline the product establishment and material file association process, improve the user's ability to filter and search for items in their registration and product listing, and include the ability to export and/or generate PDFs of your information.

3. Pre-requisite for TRLM Access

To initiate TRLM registration process electronically, the owner, operator, or authorized agent of a tobacco establishment must have a FDA Unified Registration and Listing System (FURLS) account with access to TRLM.

To create a new online account, please follow the step-by-step instructions from the link below:

https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm114181.htm

Make a note of your account identification number. You will need it, along with the password you selected to login to your account in the future.

Existing OAA accounts for Medical Device Registration and Listing or Food Facility cannot be used to register tobacco products. In such a case, you must create a separate account for TRLM.

4. TRLM Login

To access TRLM, follow the steps below:

1. Log into FURLS using your account identification number and password.

2. Select the Tobacco Registration and Listing System from the list of systems available on the FURLS homepage (see Figure 1).
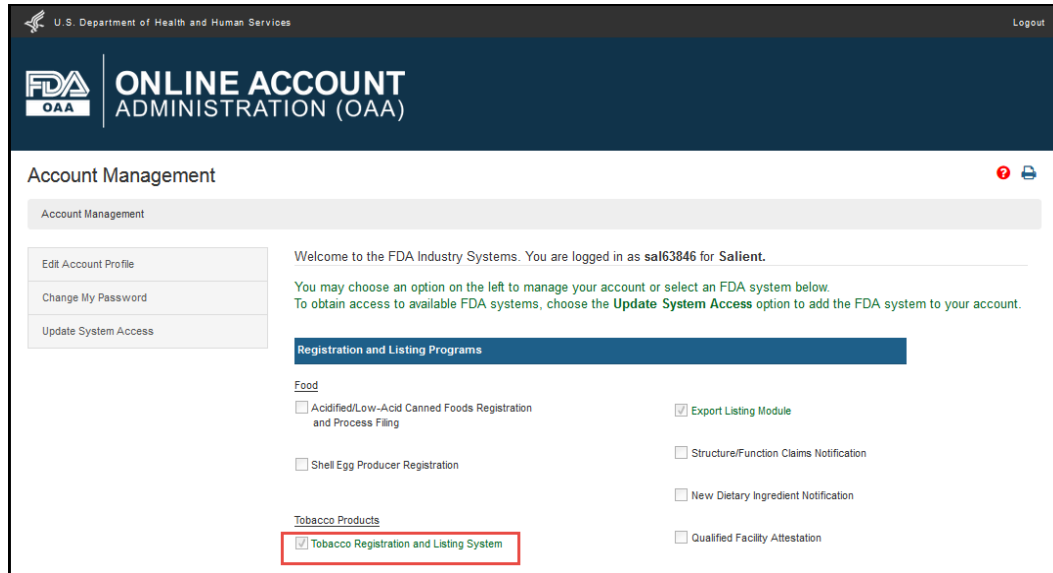

Figure 1

3. Once selected, you will automatically be navigated to the TRLM homepage (see Figure 2).
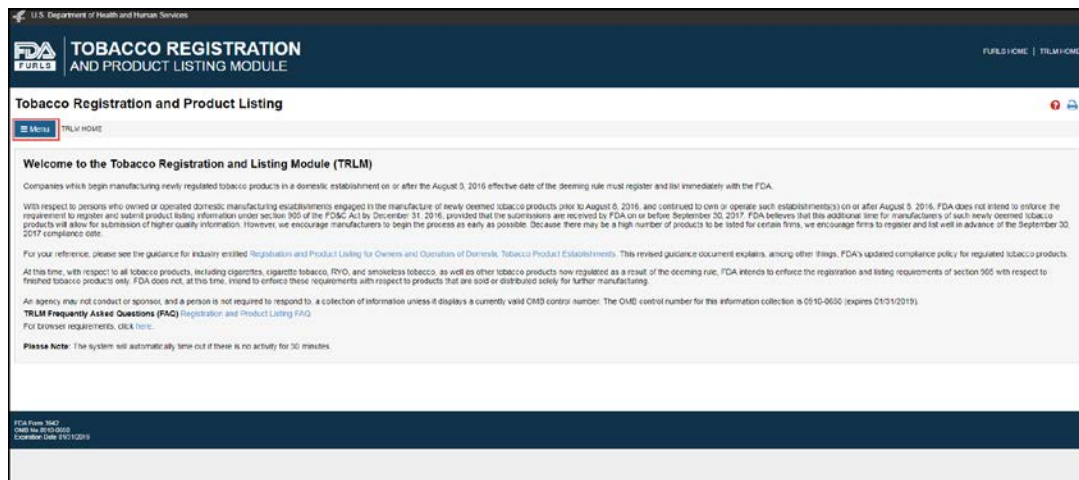

Figure 2

5. TRLM Key Features

When you select the Menu button from the homepage, you will see five (5) TRLM options (see Figure 3). Below is a brief description of the options:

Options	Description
TRLM Home	This link will take you back to the TRLM homepage.
Registration	This link will allow you to enter a new registration, update an existing registration, or perform the required annual registration updates.
Downloads	This link will take you to the generated files. NOTE: The system will only show you the generated files as of October 29, 2018.
Change Log	This link will display a log of all your updates made to your account and/or establishment. NOTE: The system will only show you the updates starting October 29, 2018.
Additional Resources	This link will provide you access to other resources, such as the FDA Form 3741/3741a, Webinars, and other useful links.

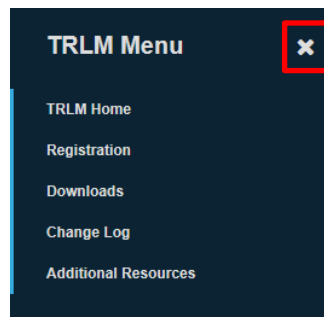To close the TRLM Menu, click on the "X" icon (see Figure 3).

Figure 3

6. New Registration

To initiate a new registration, select "Registration" from the TRLM Menu (see Figure 4).
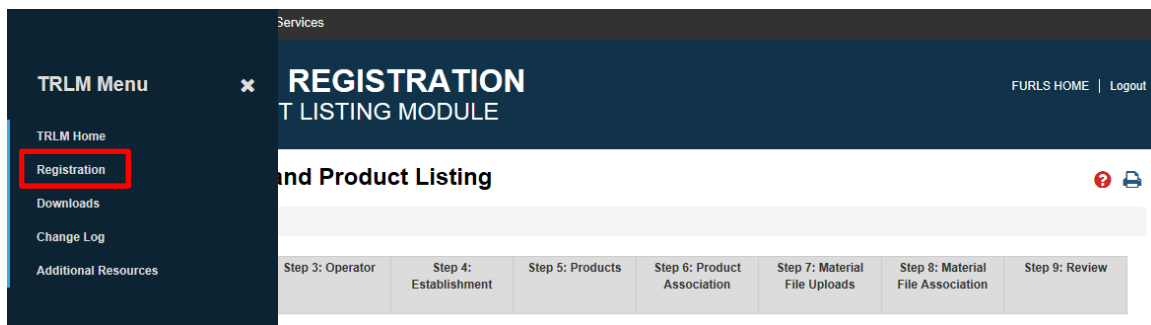
Figure 4

Once you have selected the "Registration" option from the TRLM menu, you will be directed to Step 1: Identification (see Figure 5).
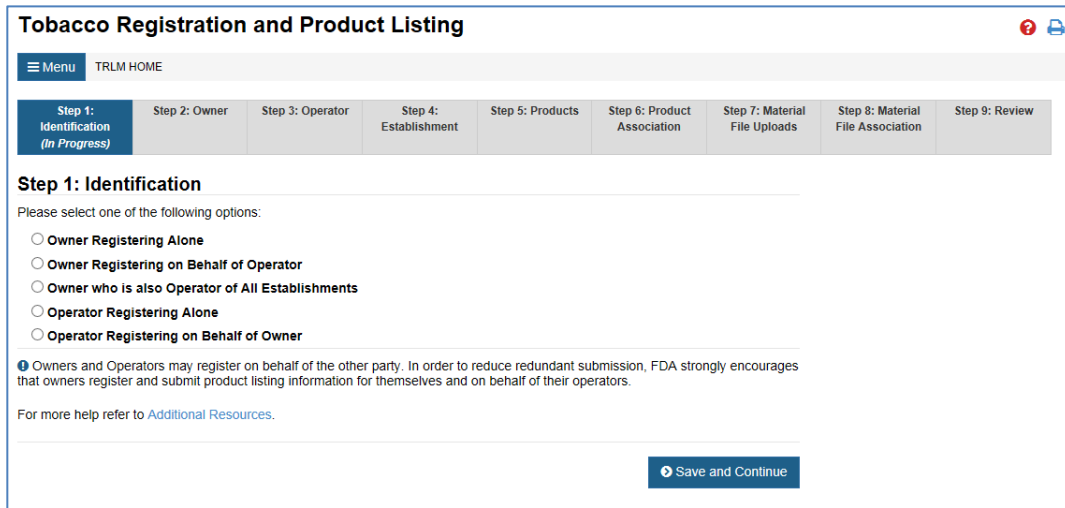

Figure 5

NOTE: You will be able to jump to any completed step within the registration. One way to tell if a step is completed is the tab is colored green or red. There are also icons that correspond to the green or red tab color. As a rule, remember to click on the "Save and Continue" button on each step to save your work for later.

Step 1: Identification

1. For a new registration, the identification selected in Step 1 will show or not show the following options:

Submitter Type	Description
Owner Registration Alone	The system will not display the operator information or operator business structure.
Owner Registering on Behalf of Operator	The system will only display the operator information and operator business structure.
Owner who is also Operator of all Establishments	The operator information and operator business structure will automatically be populated using the Owner's information.
Operator Registering Alone	The system will not display Section 2A: Registration (Owner Information) and Section 2B: Registration (Owner Business Structure) pages.
Operator Registering on Behalf of Owner	The system will not display Section 2A: Registration (Owner Information) and

| | Section 2B: Registration (Owner Business Structure) pages. |

2. Once you have selected an identification, click the "Save and Continue" button to go to the next step.

Step 2: Owner Information

1. Enter the required information in Section 2A: Owner Information (see Figure 6) or you can click on the "Auto-Fill from Account Information" on the top, right-hand side (see Figure 6), which will automatically fill in the relevant information from your FURLS account information.

Tobacco Registration and Product Listing

☰ Menu   TRLM HOME

| Step 1: Identification ✓ | Step 2: Owner (In Progress) | Step 3: Operator | Step 4: Establishment | Step 5: Products | Step 6: Product Association | Step 7: Material File Uploads |

Section 2: Owner Registration

For more help refer to Additional Resources.

Section 2A - Owner Information

Auto-Fill from Account Information

Owner Information

Owner Name (Name of the Corporation/Partnership or Individual Owner)

Address Line 1

Address Line 2 *(Optional)*

Optional

Country

Please Select

ZIP or Postal Code

City (NonUS)

State, Province or Territory

Please Select

Owner Headquarters D&B DUNS Number *(Optional)*

Optional

Owner Point of Contact *(Optional)*

Title

Please Select

First/Given Name

Optional

Middle Name

Optional

Last Name

Optional

Position Title

Optional

Email Address

Optional

Telephone (Include Country Code if applicable)

Country | Area | Phone | Ext

Fax

Country | Area | Fax

Figure 6

2. Enter the required information in Section 2B: Registration (Owner Business Structure) (see Figure 7).

Figure 7

3. Below is a brief description of your options for the business structure:

Options	Description
Sole Proprietorship	Enter the Owner's first and last name.
Partnership	Enter at least two partner names. If there are more than two partners, click the Add Another Partner button and list them accordingly.
Corporation	Enter the name of each Corporate Officer or Director in the field labeled First Name of the Officer/Director and Last Name of the Officer/ Director. You can click the Add Corporate Officer or Director button to add more names. In the next field, identify the state of incorporation. You can add additional information in the free-text box underneath the "Please describe further."

4. Select the type of business structure and provide the necessary information.

5. Answer the "Does the Owner do business by another name?" question. If YES, enter the necessary information.

6. Answer the "Do you want to add Brand Owner information?" question. If YES, enter the brand owners by clicking on the "Add Brand Owner" button.

7. Once you have entered the required information in section 2B, click on the "Save and Continue" button to go to the next step.

8. The system will automatically perform an address validation to all the addresses entered in the system (see Figure 8).

    a. If the address entered is found to be valid, no action is needed.

b. If there are minor differences between the provided address and the validated address, the system will display the validated address next to the provided address (see Figure 8).

Address Validation

Owner Address

WARNING: This address has been verified; however minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made, or correct the address yourself.

Provided Address	Validated Address
Address Line 1 1901 Research	**Address Line 1** 1901 Research Blvd
Address Line 2	**Address Line 2**
City Rockville	**City** Rockville
State MD	**State** MD
ZIP or Postal Code 20850	**ZIP or Postal Code** 20850-3164
Country UNITED STATES	**Country** UNITED STATES

◀ Edit Address   **▶ Accept Validated Address**

Figure 8

9. You can make changes to the entered address by selecting the "Edit Address" button, or you can select the "Accept Validated Address" button to proceed.

10. If the address entered cannot be verified, the system will display a warning message. You will then be navigated to Section 3A: Operator Information or to Step 1: Identification, if you selected the submitter type as Operator Registering Alone.

Step 3: Operator

1. Enter the required information in Section 3A: Operator Information (see Figure 9) or you can click on the "Auto-Fill from Account Information" on the top, right-hand side (see Figure 9), which will fill in the relevant information from your FURLS account information.

Section 3: Operator Information

Information for multiple operators may be submitted if you are registering on their behalf.

For more help refer to Additional Resources.

Section 3A - Operator Information

Auto-Fill from Account Information

Operator Information	Operator Point of Contact *(Optional)*
Operator Name	**Title**
	Please Select
Address Line 1	**First/Given Name**
	Optional
Address Line 2 *(Optional)*	**Middle Name**
Optional	Optional
ZIP or Postal Code	**Last Name**
	Optional
City	**Position Title**
Please Select	Optional
State, Province or Territory	**Email Address**
Please Select	Optional
Operator Headquarters D&B DUNS Number *(Optional)*	**Telephone (Include Country Code if applicable)**
Optional	1 / Area / Phone / Ext
	Fax
	1 / Area / Fax

Figure 9

2. Enter the required information in Section 3B - Registration (Owner Business Structure) (see Figure 10).

Section 3B - Operator Business Structure

Select the type of business structure and provide indicated information.

○ Sole Proprietorship
○ Partnership
○ Corporation

Does the Operator do business by another name?

○ Yes   ○ No

⊙ Add to Operator's List

⊙ Previous   ✖ Discard Draft   ⊙ Save and Continue

Figure 10

3. Below is a brief description of your options for the business structure:

Options	Description
Sole Proprietorship	Enter the Owner's first and last name.
Partnership	Enter at least two partner names. If there are more than two partners, click the Add Another Partner button and list them accordingly.
Corporation	Enter the name of each Corporate Officer or Director in the field labeled First Name of the Officer/Director and Last Name of the Officer/ Director. You can click the Add Corporate Officer or Director button to add more names. In the next field, identify the state of incorporation. You can add additional information in the free-text box underneath the "Please describe further."

4. Answer the "Does the Owner do business by another name?" question. If YES, enter the business name(s). Additional names can be added by clicking on the "Add Another Business Name" button.

5. Once you have completed this section, click on the "Add to Operator's List" button (see Figure 10) to update the Operators List (see Figure 11).

Figure 11

6. From the Operators List, you can EDIT an Operator's information by clicking on the edit icon or DELETE an operator by clicking on the delete icon in the Action column.

7. Additional operators can be added by clicking on the "Add New" button.

8. Once you have entered the Operator's information, click the "Save and Continue" button to go to the next step.

   NOTE: The above is not displayed if you selected the submitter type as "Owner who is also Operator of All Establishments" in Step 1 of the identification.

Step 4: Establishment

1. Enter the required information for both the Establishment Information and Establishment Point of Contact (see Figure 12).
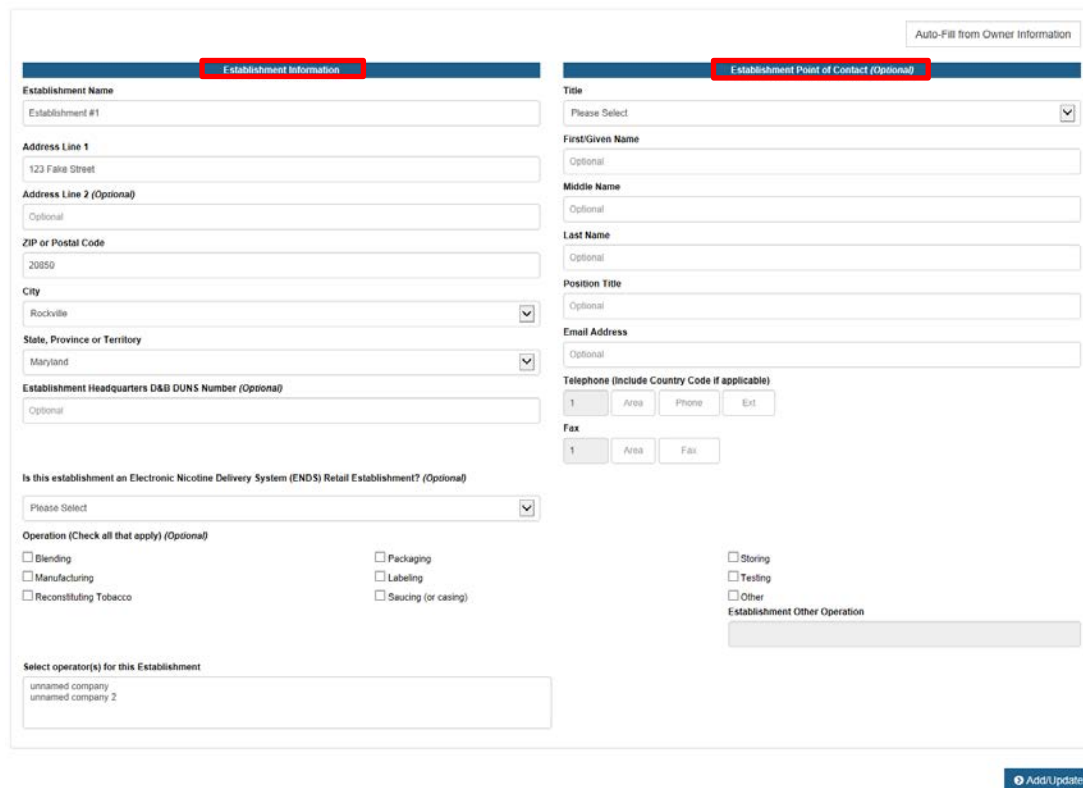

Figure 12

2. You can click on the "Auto-Fill from Owner Information" on the top, right-hand side, which will fill in the relevant information from the previous section. You can change the pre-filled information as necessary.

3. You can respond to the optional question of "Is this an Electronic Nicotine Delivery System (ENDS) Retail Establishment?"

4. Select the appropriate operation(s) of your establishment. Please keep in mind that you can select multiple operations.

5. When the registration has more than one operator, select at least one operator from the Select Operator(s) for this Establishment dropdown menu.

6. Once you have completed this section, click the "Add/Update" button to submit the information (see Figure 12).

7. A list of your establishment will be displayed as shown below (see Figure 13).

Section 4: Establishment Information

The following establishment(s) have been entered. You may add another establishment by clicking the "+Add New" Button above the Establishment registration or continue to complete your registration by clicking the "Save and Continue" button.

For more help refer to Additional Resources.

Establishment List   ➕ Add New

Action	Establishment Name	Address	Operations	
	▽	▽	▽	
✎ ✖	Test Company 4	555 eight lane Rockville,…	Manufacturing, Testing	
✎ ✖	Test Company 1	111 twenty two jump stre…	Packaging, Manufacturing	

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⬅ Previous   ✖ Discard Draft   Save and Continue ➤

Figure 13

8. From the Establishment List, you can EDIT an establishment information by clicking on the ✎ edit icon or DELETE an establishment by clicking on the ✖ delete icon in the Action column.

9. Additional establishments can be added by clicking on the "Add New" button.

9. Once you have entered the establishment information, click the "Save and Continue" button to go to the next step.

Adding a New Establishment

After you have submitted your registration and product listing (meaning you have gone through the Confirmation Statement), you can add more establishments.

To do so, please follow the steps below:

1. Go to Step 4 of your registration.
2. Click on the "Add New" button.

3. Enter the necessary information and click on the "Add/Update" button.

4. A list of your establishment will be displayed, and Step 6 will change color from green to red.

5. To change the tab from red to green color, you must associate the new establishment to products by going to step 6.

Step 5: Products Listing

The in-browser table grid has been improved to allow more functionalities (e.g., sorting, filtering, moving of columns, error indicators, etc.) to help improve the process of entering your product listing(s) information into the system.
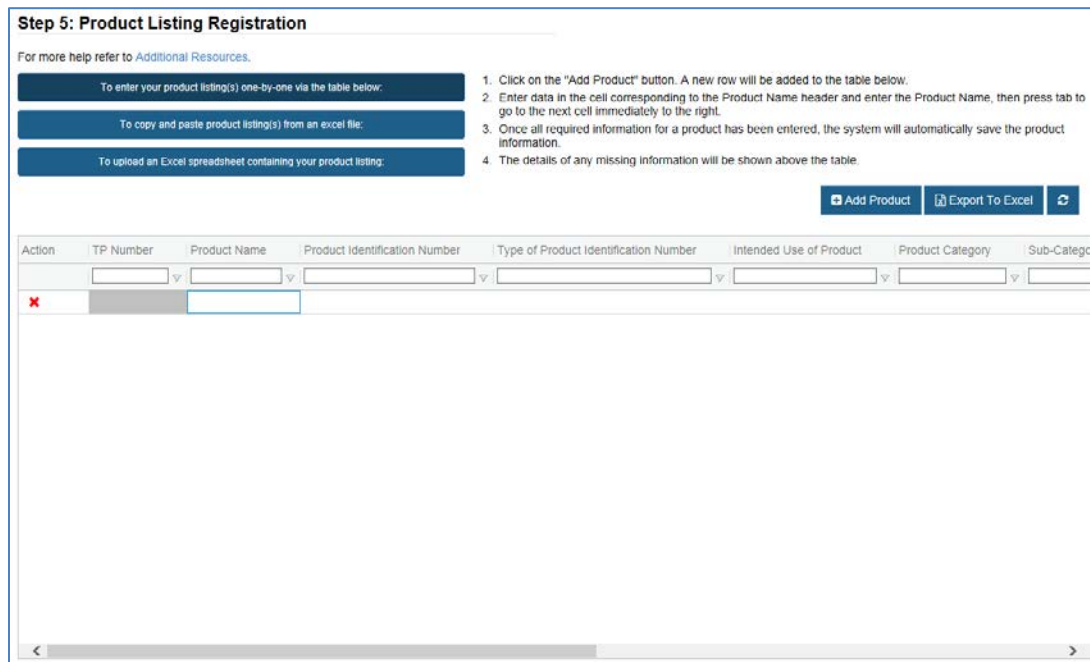
To understand the functionalities of the in-browser table grid, please refer to Appendix of the User Guide. The functionalities are available wherever you see a table grid.

There are three (3) different ways you can enter your product listing: (1) Enter them manually, (2) Copy and paste them into the table grid, or (3) Upload an Excel spreadsheet to the system.

Once you click on a method, a list of directions will be displayed on the right-hand side (see Figure 14).

Option 1: Enter Product Listing Information Manually

You can enter the product information manually one-by-one using the table grid below (see Figure 14). To do so, please follow the steps below:
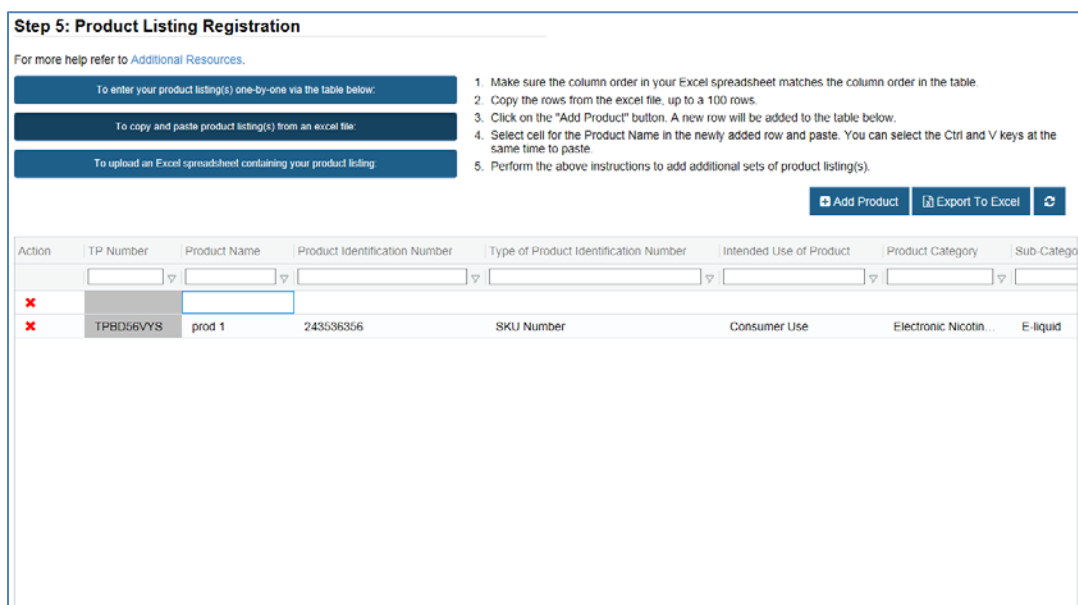

Figure 14

1. For each product that you want to enter, click on the "Add Product" button. The system will automatically add a new row to the table.

2. Start entering your information underneath the "Product Name" column on the new row, and then use the Tab key, arrow keys, or your mouse to go to the next column.

3. You can use the Enter key or double click on your mouse to show the options within the column.

4. After entering the required information about your product, the system will automatically save the product and assign it a Tobacco Product (TP) number.

   NOTE: The TP number is generated by the system, therefore the TP column will be "grayed out" until the required information for the product has been completed. The TP number cannot be modified by the user.

Option 2: Enter Product Listing Information via Copy and Paste

You can copy and paste from an Excel spreadsheet onto the table grid. This method allows you to copy and paste up to 100 products at a time.

In order for this to work, the columns from your Excel spreadsheet MUST match the columns listed and be in the same order as the table grid (see Figure 15).

Figure 15

NOTE: The Product Name, Intended Use of Product, Product Category, and Sub-Category are the ONLY required fields. However, it is highly recommended that all the other columns be included in your Excel spreadsheet, even if these columns do not have any information in them.

To copy and paste your information to the table grid, please follow the steps below:

1. Highlight the information (up to 100 rows) in your Excel spreadsheet, then right-click and select Copy (or press Ctrl/C).

2. Click on the "Add Product" button to create a new row in the table grid.

3. Select the empty row underneath the "Product Name" cell.

4. Place the cursor inside this field and paste the copied data (or press Ctrl/V).

5. If there are errors with the pasted data (i.e., missing cells and/or invalid data), the system will display the appropriate error message(s). Corrections are needed for the error message(s) to disappear.

6. If there were no errors with the pasted data, wait until the system processes the information. You may see a message stating "Please wait while your rows are loading".

7. You may want to click on the "Refresh Data Table" every so often to help the system process the information.

Option 3: Enter Product Listing Information by Uploading Excel File(s)

You can upload your Excel file(s) to the system for processing. This method allows up to 250,000 products/rows (file size cannot be larger than 50MB) to be uploaded (see Figure 16).

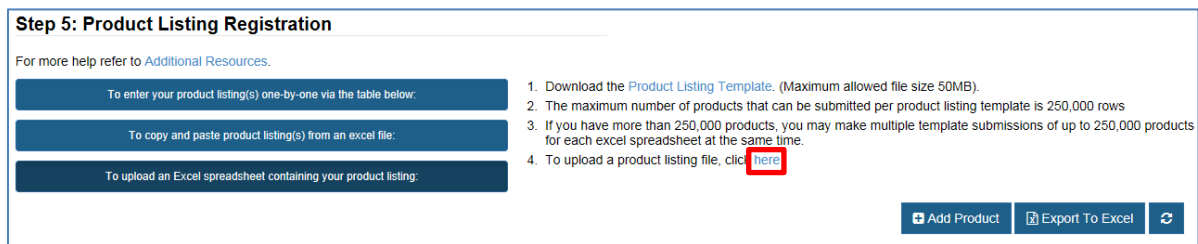**Figure 16**

NOTE: Before using this method, first download a Product Listing Template by clicking on the link (see Figure 16). You can save this template onto your computer and work on it offline.

To upload your Excel file(s) to the system for processing, please follow the steps below:

1. Click on the "here" on step number four (4) from the on-screen instructions (see Figure 16).

2. The system will display the Product Listing Template Upload pop-up window for you to begin the upload process (see Figure 17).
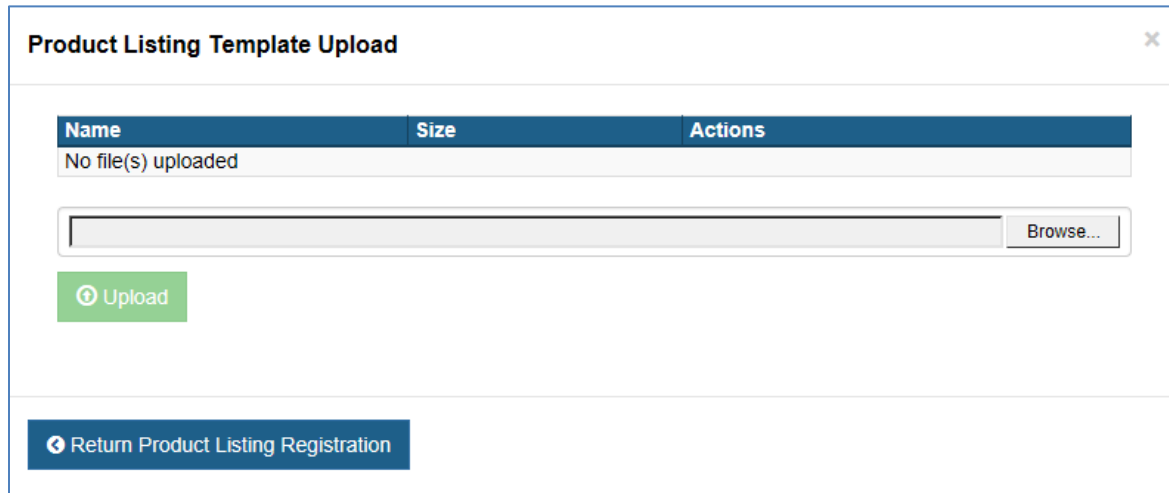

Product Listing Template Upload   ✕

Name	Size	Actions
No file(s) uploaded		

Browse...

⊕ Upload

❮ Return Product Listing Registration

Figure 17

3. Click on the "Browse" button and find your Excel file(s) from your computer.

4. You can single or multi select your file(s). Once the file(s) have been selected, click on the "Open" button.

5. A list of your file(s) will appear on your screen. Confirm the list and click on the "Upload" button.

6. The system will upload your selected file(s) and will add the file(s) to the system for processing. Below is a description of the various status:

Status	Description
Pending	Your file has been uploaded and is awaiting to be processed. If necessary, you can delete/remove the file(s).
Processing	Your file is being processed by the system. You cannot remove the file once it has started processing.
Complete	Your file has been processed and you should see your product(s) listed on the table grid. If you do not see your products on the table grid, click on the Refresh Data Table button above the table grid. The file will be removed from the uploaded file table after 24-hours.
Error	There were issues found with your file(s). Please check your email for the details of the errors in the uploaded file. The file will be removed from the uploaded file table after five (5) days.

NOTE: All uploaded files regardless of the number of products in the spreadsheet will be processed by the system offline. An email notification will be sent to you when the offline process has been completed.

7. Once you have completed the information for your products, click on the "Save and Continue" button to go to the next step.

NOTE: Every active establishment in TRLM MUST have at least one product listed in their table grid.

Step 6: Product Association

This step allows you to identify your products to your establishment(s). However, if you have one establishment, the system will automatically associate your products to the one establishment, skipping step 6 and taking you to step 7.

There are two key features to this section (see Figure 18). Both are there to help you understand your products and establishments:

Features	Description
Products Not Associated to Establishment(s)	This will show the total number of products that have not been associated to any establishment.
Establishment(s) without Products	This will show the number of establishments that do not have any products listed associated to them.

In the example below, there are 1,670 products that need to be associated with the two (2) establishments (see Figure 18).

Step 6: Product Association

ⓘ Select establishments to associate to product listing(s). You can associate product listing(s) using the Edit Associations button. Changes will be saved automatically. All products must be associated to at least one establishment. All establishments must have at least one product.

For more help refer to Additional Resources.

All Product Listings must be associated with an Establishment.

Products Not Associated to an Establishment: 1670–Show Unassociated Product Listings
Establishments without Products: 2–Show Unassociated Establishments

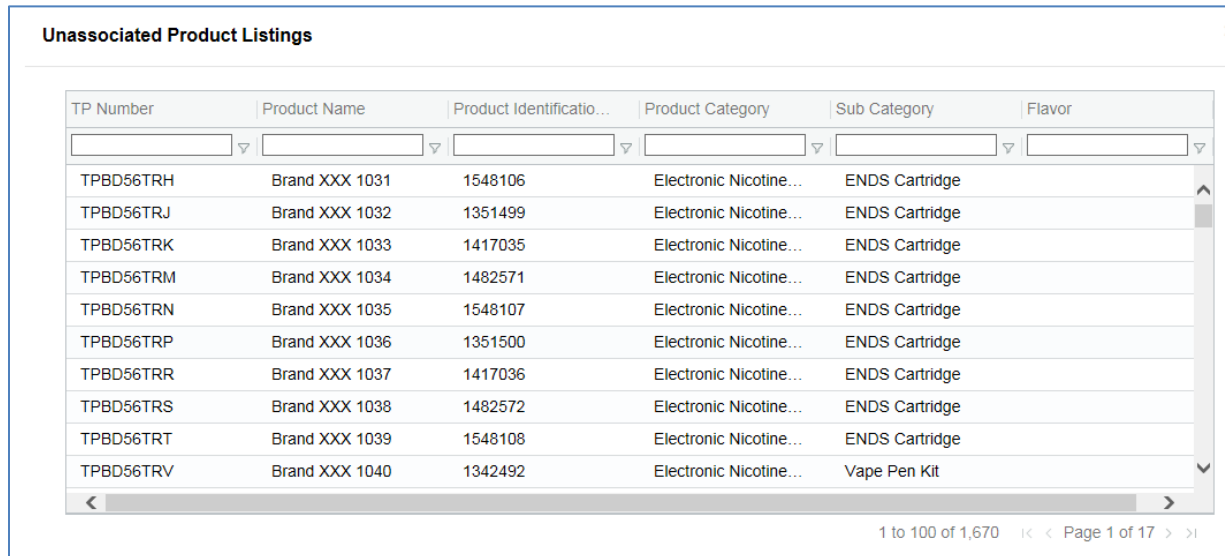| Select	Establishment Name	Establishment Address	City	State	Zip
☐	example company 1	1901 Research Blvd	Rockville	MD	20850
☐	example company 2	1455 Research Blvd	Rockville	MD	20850

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❯ Edit Association(s)   ❯ View Association(s)

❮ Previous   ✕ Discard Draft   ❯ Save and Continue

Figure 18

You can click on the "Show Unassociated Product Listings" to see the products that need to be associated. A list will be display as shown below (see Figure 19).
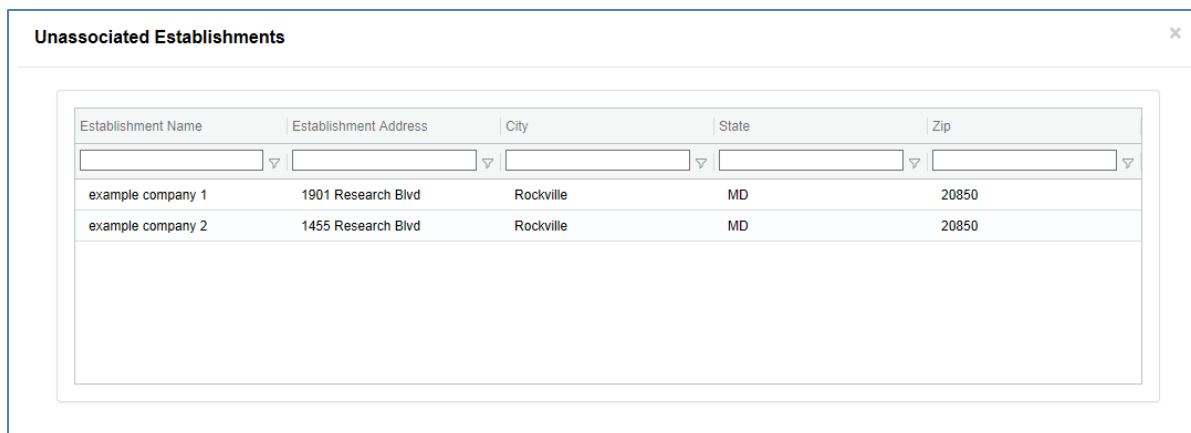

Unassociated Product Listings

TP Number	Product Name	Product Identificatio…	Product Category	Sub Category	Flavor
TPBD56TRH	Brand XXX 1031	1548106	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRJ	Brand XXX 1032	1351499	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRK	Brand XXX 1033	1417035	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRM	Brand XXX 1034	1482571	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRN	Brand XXX 1035	1548107	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRP	Brand XXX 1036	1351500	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRR	Brand XXX 1037	1417036	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRS	Brand XXX 1038	1482572	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRT	Brand XXX 1039	1548108	Electronic Nicotine…	ENDS Cartridge	
TPBD56TRV	Brand XXX 1040	1342492	Electronic Nicotine…	Vape Pen Kit	

1 to 100 of 1,670 |< < Page 1 of 17 > >|

Figure 19

You can click on the "Show Unassociated Establishments" to see a list of establishments without a product associated to them (see Figure 20).

Unassociated Establishments

Establishment Name	Establishment Address	City	State	Zip
example company 1	1901 Research Blvd	Rockville	MD	20850
example company 2	1455 Research Blvd	Rockville	MD	20850

Figure 20

To close the window, click on the "X" in the upper right-hand corner.

The user will need to associate the products to an establishment. Once everything has been associated, the numbers next to the "Products Not Associated to an Establishment" and "Establishments without Products" will be updated to zero (0). When both values are at zero (0), the user can continue to the next step.

If either the product or establishment is greater than zero (0), the "Save and Continue" button will be grayed out or disabled.

To associate your products and establishments, please follow the steps below:

1. To associate your products to an establishment(s), select one or more of your establishments by checking the boxes underneath the "Select" column (see Figure 21).

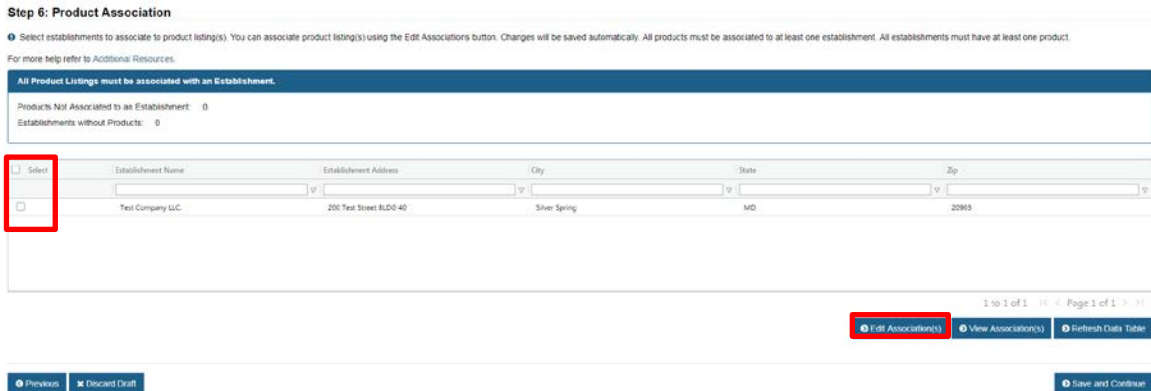2. Click on the "Edit Association" button (see Figure 21).

Figure 21

3. On the Edit Product Association widow, you will see the establishment(s) selected at the top of the page, along with the first 100 products, which you can perform the association.
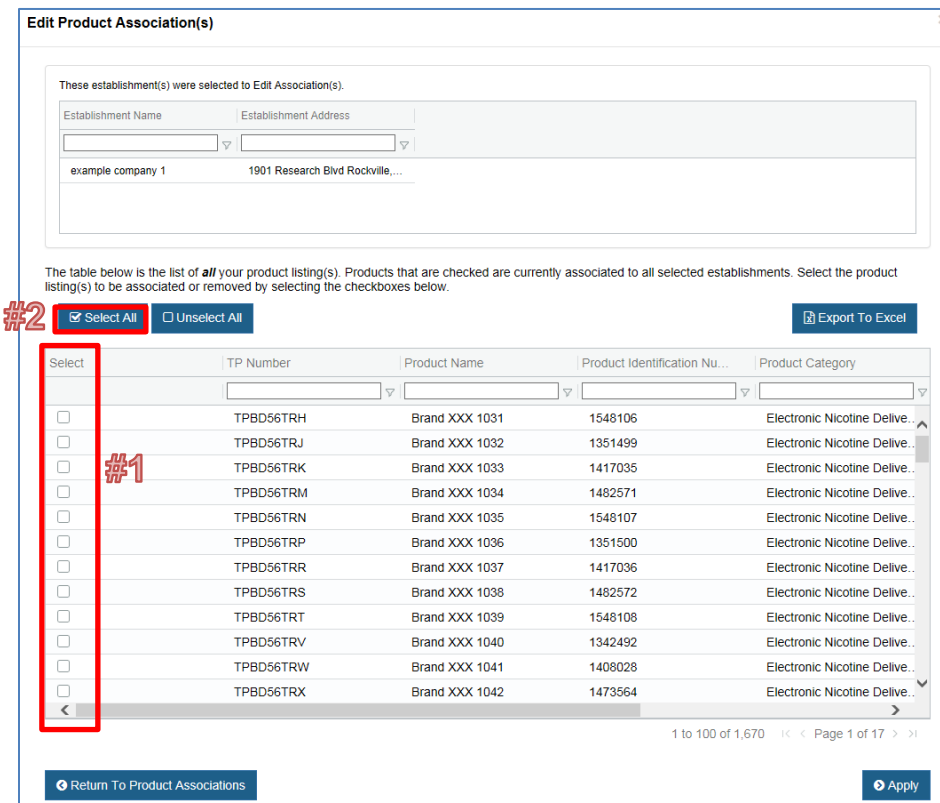

Figure 22

4. Be sure to verify the establishment information at the top of the page before proceeding.

5. If the information is not correct, you can click on "Return to Product Association" button (see Figure 22).

6. There are three (3) ways of selecting your products to be associated (see Figure 22 and 23):

| #	Methods
1	Click on the checkbox under the Select column heading in the row for a product, and then click on the Apply button.
2	Click on the Select All button to select the products (i.e., up to 100 products) on the current page, and then click on the Apply button (see Figure 24).
3	Click on the Select all _____ products to select all your products in your account, and then click on the Apply button (see Figure 23).
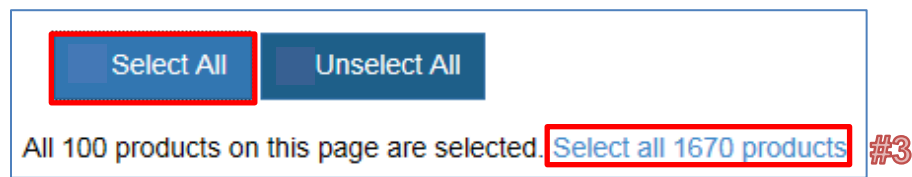
Figure 23

7. Once you have selected your products, click on the "Apply" button (see Figure 22).

8. If your association requires an offline processing, a message will appear on your window and you will receive an email notification once the process has been completed.

   NOTE: While the system works on this product association, you can work on other product associations or other parts of your registration that have been unlocked.

9. To view an existing association, select an establishment and click on the "View Association(s)" button from the Product Association screen (see Figure 24).

Step 6: Product Association

ⓘ Select establishments to associate to product listing(s). You can associate product listing(s) using the Edit Associations button. Changes will be saved automatically. All products must be associated to at least one establishment. All establishments must have at least one product.

For more help refer to Additional Resources.

All Product Listings must be associated with an Establishment.

Products Not Associated to an Establishment: 0

Establishments without Products: 0

☐ Select	Establishment Name	Establishment Address	City	State	Zip
☐	establishment #2	123 fake st, suite 251	Rockville	MD	20850
☐	Location #1	342 fake st, suite 250	Rockville	MD	20850

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❯ Edit Association(s)   ❯ View Association(s)   ❯ Refresh Data Table

❮ Previous   ✖ Discard Draft   ❯ Save and Continue

Figure 24

NOTE: If you select multiple establishments to view association, a list of products that are jointly associated to the establishments selected may be displayed.

Step 7: Material File Uploads

This step allows you to upload your material files such as your product labels, advertising, and/or consumer information.

To upload your material files, please follow the steps below:

1. Click on the "Choose File" button near the bottom of the screen (see Figure 25).

Please select all of the files you want to upload and click Upload. Each uploaded file is limited to 2 GB. You can upload a single file or multiple files at the same time.

The acceptable files include pdf, gif, jpeg, jpg, tiff, wmv, avi.

All uploaded files will be added to the table above. You will be able to add details to the advertising, labeling, consumer information by editing the row in the table above.

Name	Size	Progress	Actions
No file(s) uploaded			

Choose Files No file chosen

⊕ Upload

Figure 25

2. Find your file(s) from your computer. Once you have found your file(s), click on the "Open" button.

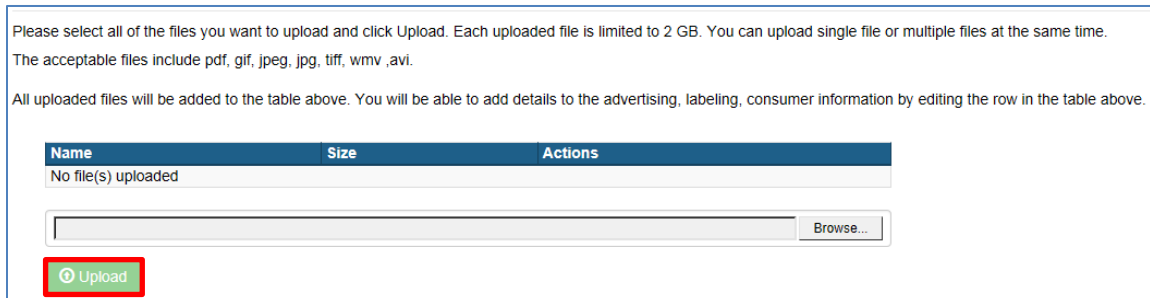3. Click on the "Upload" button to start the uploading process (see Figure 26).

Please select all of the files you want to upload and click Upload. Each uploaded file is limited to 2 GB. You can upload single file or multiple files at the same time.

The acceptable files include pdf, gif, jpeg, jpg, tiff, wmv ,avi.

All uploaded files will be added to the table above. You will be able to add details to the advertising, labeling, consumer information by editing the row in the table above.

Name	Size	Actions
No file(s) uploaded		

[ ] Browse...

[⊕ Upload]

Figure 26

4. All uploaded file(s) will be displayed on the screen as the system processes the request (see Figure 27).

Step 7: Material File Uploads

ⓘ Please upload all files for your account. You will be able to associate them to product listing(s) in the next step.

For more help refer to Additional Resources.

[Ⓧ Export To Excel]

Action	File Name	Material Category	Type of Material (Optional)	Title (Optional)	Unique ID or Internal ID (O...	UPC C
▽	▽	▽	▽	▽	▽	
📄✖	Penguins.jpg	Labeling				
📄✖	Lighthouse.jpg	Labeling				

1 to 2 of 2 |< < Page 1 of 1 > >|

Figure 27

NOTE: Each file must be less than 2GB in size and file type/extension MUST be one of the acceptable formats: pdf, gif, jpeg, jpg, tiff, wmv, or avi.

5. Complete the "Material Category" column. All the other columns are optional information.

6. Once you have finished entering your information for each file, click on the "Save and Continue" button to go to the next step.

Step 8: Material File Association

This step allows you to associate your material file(s) such as your product labels, advertising, and/or consumer information to your products.

To associate your material file(s) to your products, please follow the steps below:

1. After uploading your material file(s), the system will automatically list your uploaded file(s) (see Figure 28).
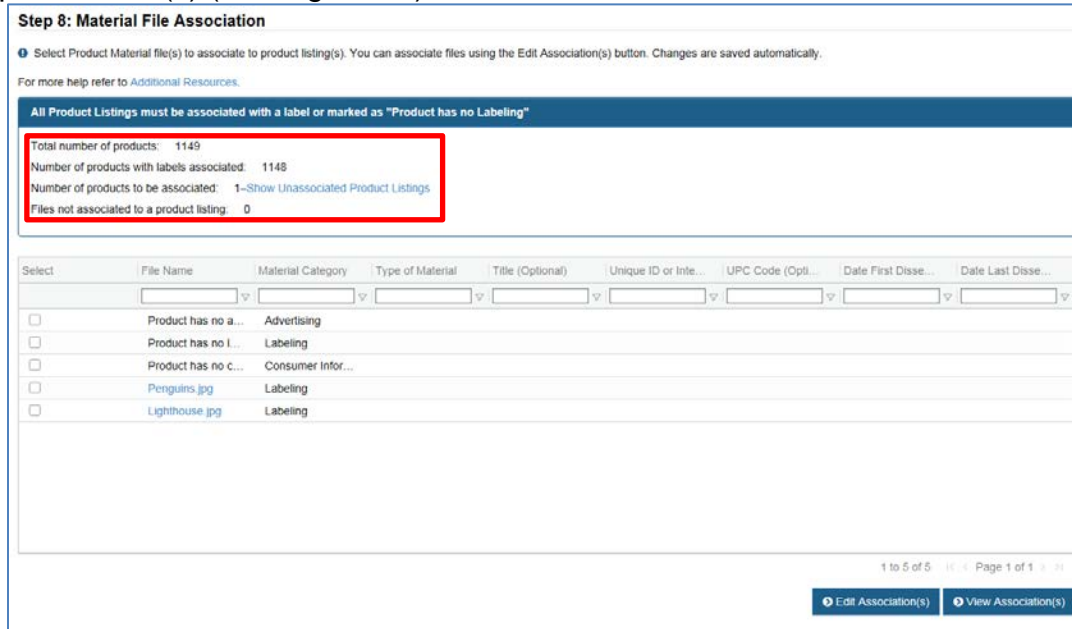

Figure 28

2. On the top portion of the window, you will see the following items about your products and material files (see Figure 28):

Information	Description
Total Number of Products	The total number of products in your account.
Number of Products with Labels Associated	This is the number of products that have labels associated to them.
Number of Products to be Associated	This is the number of product that need to be associated. Click on the Show Unassociated Product Listing link to see the products.
Files not Associated to a Product Listing	These are the files that need to be associated to a product. Click on the Show Unassociated Files link to see the files.

3. You can select one or multiple files by checking the checkbox(s) underneath the "Select" column, and then clicking on the "Edit" button (see Figure 29).

Figure 29

4. A list of your products will be displayed (see Figure 30). You can individual select your products or use the "Select All" or "Unselect All" buttons on top of the table grid.

Figure 30

5. If you click on the "Select All" button, you will have the option to select all your products at one-time (see Figure 31).

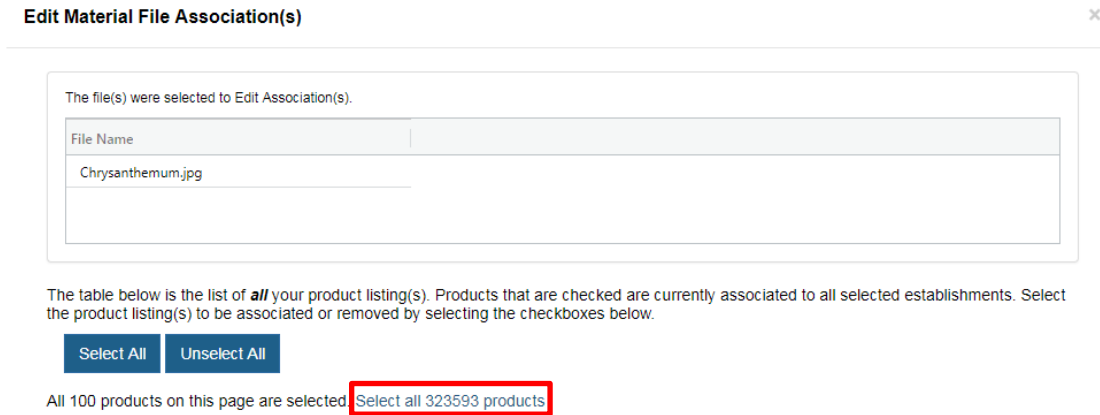**Edit Material File Association(s)**   ✕

The file(s) were selected to Edit Association(s).

File Name	
Chrysanthemum.jpg	

The table below is the list of *all* your product listing(s). Products that are checked are currently associated to all selected establishments. Select the product listing(s) to be associated or removed by selecting the checkboxes below.

[Select All] [Unselect All]

All 100 products on this page are selected. Select all 323593 products

Figure 31

6. Once you have selected your products, click on the "Apply" button (see Figure 32).

7. To go back to the previous screen, click on the "Return to Material Association" button.

Edit Material File Association(s)   ✕

The file(s) were selected to Edit Association(s).

File Name	
Chrysanthemum.jpg	

The table below is the list of *all* your product listing(s). Products that are checked are currently associated to all selected establishments. Select the product listing(s) to be associated or removed by selecting the checkboxes below.

[Select All] [Unselect All]

All 100 products on this page are selected. Select all 323593 products

Select	TP Number	Product Name	Product Identification Number	Product Category
☑	TPBMJ7ZJB	UAT Test Product 243410	CL17M133C950C12N040M030	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJC	UAT Test Product 243411	CL17M133C950C12N040M050	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJD	UAT Test Product 243412	CL17M133C950C12N040M060	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJF	UAT Test Product 243413	CL17M133C950C12N040M120	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJG	UAT Test Product 243414	CL17M133C950C12N040M240	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJH	UAT Test Product 243415	CL17M133C950C12N080M015	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJJ	UAT Test Product 243416	CL17M133C950C12N080M030	Electronic Nicotine Delivery Sys.
☑	TPBMJ7ZJK	UAT Test Product 243417	CL17M133C950C12N080M050	Electronic Nicotine Delivery Sys.

1 to 100 of 323,593 |< < Page 1 of 3,236 > >|

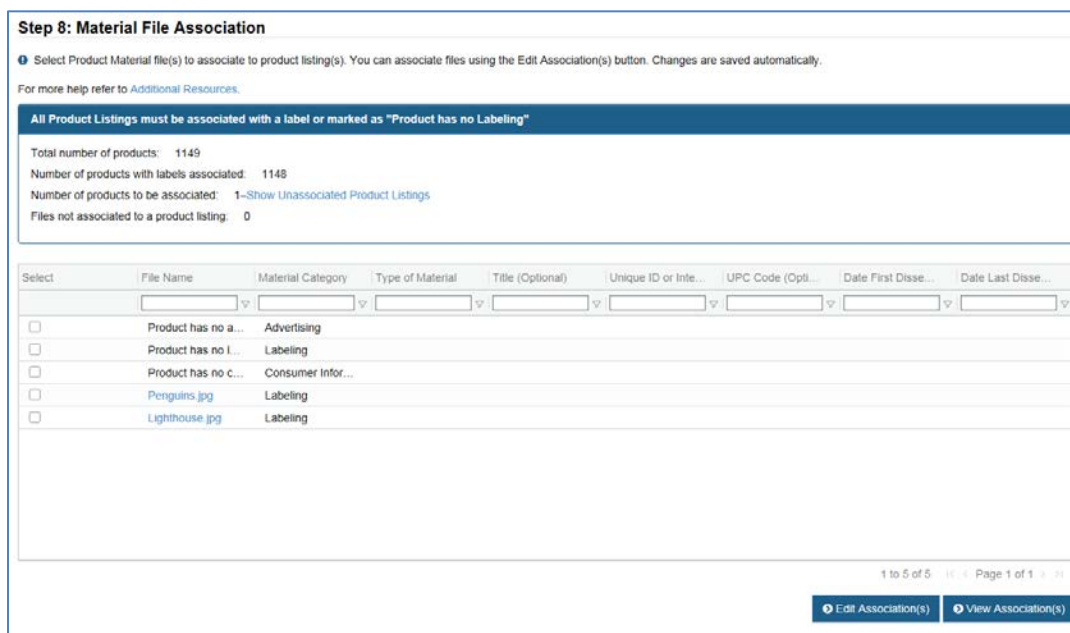[◀ Return to Material File Association]   [❯ Apply]

Figure 32

8. If your association requires offline processing, a message will appear on your window and you will received an email notification once the process has been completed.

   NOTE: While the system works on this material file association, you can work on other material file associations or other parts of your registration.

9. Products that do not have file(s) associated with them can be marked as Product has no Labelling, Product has no advertising, and/or Product has no consumer information.

   NOTE: All products MUST be associated with a product label or marked as "Product has no Labeling."

10. To see the files associated to your products, select one or multiple material files and click on the View Association(s) button. A separate window will be displayed (see Figure 33).

Figure 33

   NOTE: If you select multiple material files to view at one time, a list of products that are jointly associated to that material file will be shown.

11. In order to continue, the "Total Number of Products" and "Number of Products with Labels Associated" MUST be the same AND the "Number of Products Left to be Associated" and "Files not associated to a product listing" MUST be zero (0) (see Figure 34).

12. Click on the Save and Continue button to go to the next step.

Total number of products: 5

Number of products with labels associated: 5

Number of products to be associated: 0

Files not associated to a product listing: 0

Figure 34

NOTE: If you have products without a label or marked the Product has no Labeling, the system will automatically inactivate (after 90 days) the product if no label(s) has been associated to the product. An email reminder will be sent to you prior to the inactivation of the product(s).

Step 9: Registration Review Page

This step allows you to review your information before submitting to FDA.

Here, you can make the necessary changes by clicking on the 🖉 (Edit) icon next to the appropriate section(s) (see Figure 35).

Tobacco Registration and Product Listing

☰ Menu   TRLM HOME

| Step 1: Identification ✓ | Step 2: Owner ✓ | Step 3: Operator | Step 4: Establishment ✓ | Step 5: Products ✓ | Step 6: Product Association ✓ | Step 7: Material File Uploads ✓ | Step 8: Material File Association ✓ | Step 9: Review *(In Progress)* |

Step 9: Review

Section 1: Identification   🖉 Edit

Owner Registering Alone

Section 2: Owner Information and Business Structure   🖉 Edit

Owner Information

Owner Name (Name of the Corporation / Partnership or Individual Owner)
Test Company

Address Line 1
555 school drive

Address Line 2

Country
UNITED STATES

ZIP or Postal Code
20850

City
Rockville

State, Province, or Territory
MD

Owner Headquarters D&B DUNS Number

Owner Business Structure

Type of Business Structure
Corporation

First Name of the Officer/Director 1
John

Owner Point of Contact

Title

First / Given Name
John

Last Name
Doe

Position Title
Officer

Email Address
test@account.com

Phone Number
1 301 5551234

Fax Number

Last Name of the Officer/Director 1
Doe

Figure 35

To submit your establishment registration and product listing, including product labels, advertising, and/or consumer information, please follow the steps below:

1. Verify all the information is correct, and then click on the Save and Continue button (see Figure 36).
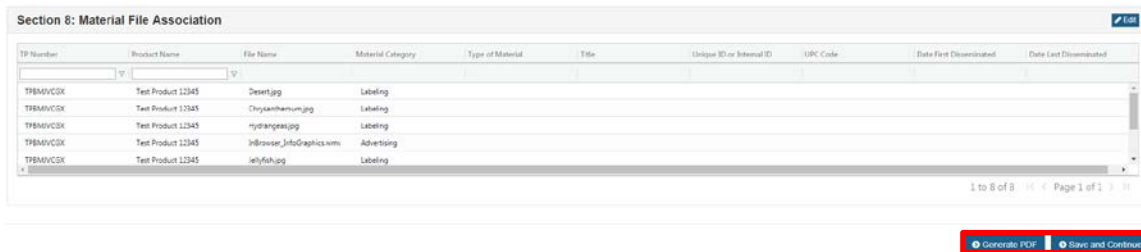

Figure 36

2. You can also select the Generate PDF button, which will PDF your registration and product listing (see Figure 36). Please look in the Download section of TRLM to see the PDF.

3. Select the Identify of the Signatory, which may include:

Identify of the Signatory	Description
Owner	The fields will be pre-filled using the contact information for the owner from Step 2, Section 2A, but can be edited.
Operator	The fields will be pre-filled with contact information for the operator from Step 3, Section 3A and can be edited. When the registration has more than one operator, you can select the operator from the drop-down list.
Authorized Agent	The fields will need to be entered by the authorized agent's contact information.
Administrative User	FDA personnel will enter their information.

4. Make all necessary changes to the Confirmation Statement screen (see Figure 37).
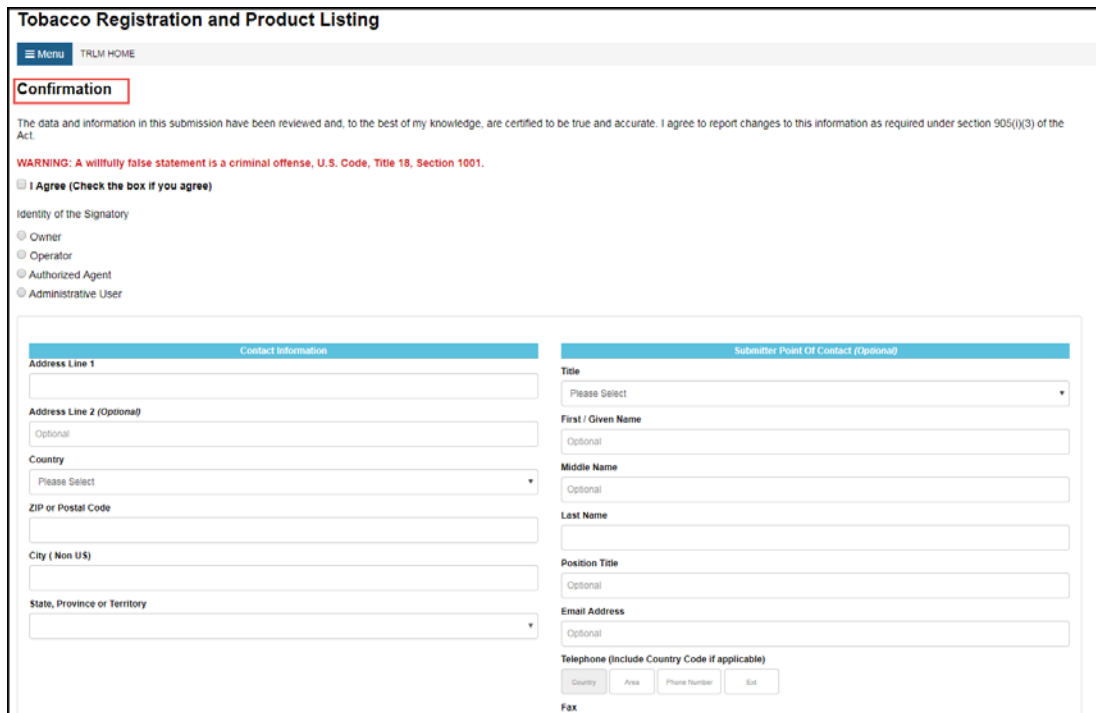
Figure 37

NOTE: You MUST agree to the Confirmation Statement to submit your registration and product listing.

5. Click on the "Submit" button.

6. The system may display the Address Validation screen, where you can either edit or accept the provided address.

7. A message will appear to let you know that your registration and product listing information has successfully been submitted.

8. To receive email notifications about your registration and product listing, please arrange your email to accept messages from CTPRegistrationandListing@fda.hhs.gov.

7. Registration and Product Listing Updates

Annual Registration

On an annual basis, you are required to review and confirm your establishment registration. The system will automatically send you an email reminder starting October 1st of each year of this requirement. In addition, the system will display a pop-up message (see Figure 38) reminding the user of this requirement.

Your annual registration update is due. Section 905(b) of the FD&C Act requires establishment registration information to be resubmitted annually on or before December 31st of each year. If you have questions this requirement, please refer to the Guidance for Industry or contact the CTPRegistrationandListing@fda.hhs.gov.

Skip and Review Later   Review

Figure 38

You can click on the "Skip and Review Later" button if you are not ready to perform the annual review. However, the system will continue to remind you of this requirement every time you log into TRLM.

If you are ready to review your establishment registration, click on the "Review" button to begin the process and follow the steps below:

1. You will be automatically navigated to Step 9, the Review page.

2. Review the information.

3. If there are no changes, find the message that reads "All the information in this account is correct and no updates are needed" (see Figure 39):

⚠ To complete your yearly registration, ensure all the information in the account is correct. If all the information is correct, select the check box below and click the submit button. To make an update to a section, click on the Edit button next to the section that needs to be updated.

☐ All the information in this account is correct and no updates are needed.
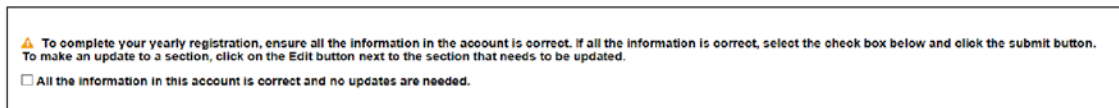
Figure 39

4. Click on the box next to the message. By checking the box, it means that you acknowledge the information listed is correct and no updates are needed.

5. If you need to make any updates, click on the ✏ Edit icon on any of the sections on the Review page. The system will automatically navigate you to the section.

   NOTE: Updating to your registration and/or product listing may trigger other tabs to change color (i.e., red). If this occurs, you MUST complete the information for those tabs for it to turn back to green.

6. If you make any changes to a section, you MUST click on the "Ready to Submit" button and complete the Confirmation Statement to submit the changes (see Figure 40).

Figure 40

7. Click on the "Save and Continue" button.

8. A message will appear to let you know that your registration and product listing information has successfully been submitted.

Establishment Status

To individually update an establishment status, please follow the steps below:

1. From your registration, go to Step 4: Establishments.

2. Locate the establishment entry and click on the Edit ( ) icon

3. Scroll towards the bottom of the page until you see the "Change Establishment Status" section.

NOTE: If your establishment is pending review or has been cancelled, you will not see the "Change Establishment Status" section. You can only change the establishment status if it is currently shown as Active or Inactive.

4. Complete the required fields and click on the "Add/Update" button.

5. The system will automatically update the establishment status and take you back to the establishment list after the "Add/Update" button has been selected.

6. Click on the "Ready to Submit" button.

7. The system will automatically take you to "Step 9: Review" page. From there, click on the "Save and Continue" button.

8. Complete the Confirmation Statement and click on the "Submit" button.

9. A "Submitted" page will appear once the system has received your information.

10. To change the establishment status from Inactive to Active, repeat steps 1 to 9.

NOTE: If you change the establishment status from Active to Inactive, the system will update the product(s) that are only associated with the establishment to Inactive and remove the associations for the product(s) that are currently associated to the establishment.

If you change the establishment status from Inactive to Active, the system will update the establishment status to Active, but you MUST

update the status of the appropriate product(s) to Active, if necessary. You can use the "Bulk Update" button on step 5 to do a mass update of your products. You <u>MUST</u> also re-associate your product(s) to your establishment.

Product Listing

After submitting your registration and product listing, you will see additional features added to the table grid. The following features include:

View Product Information

1. Click on the view (👁) icon.

2. The information about your product will be displayed (see Figure 41).

Figure 41

3. From here, you can go to the establishment (click on Go to Establishment) or product association (click on Go to Product Association) (see Figure 40).

4. Click on the "Return to Product Listing" button or the "X" on the top right-corner to close out of the window.

Make Comments

1. Click on the comment (💬) icon.

2. The comment history window will appear (see Figure 42).

Comments History ✕

Comment	Modified Date and Time	Modified By
▽	▽	▽

No Results found.

0 to 0 of 0 |< < Page 0 of 0 > >|

Apply

◁ Return to Product Listing

Figure 42

3. If you would like to add a comment about your product, type in the information in the box above the "Apply" button.

4. Click on the "Apply" button to submit the comment.

   NOTE: You are NOT allowed to remove a comment once it has been submitted.

5. Click on the "Return to Product Listing" button or the "X" on the top right-corner to close out of the window.

Product Name Change

1. Click on the product name ( ) change icon.

2. The Product Name Change History window will be displayed (see Figure 43).
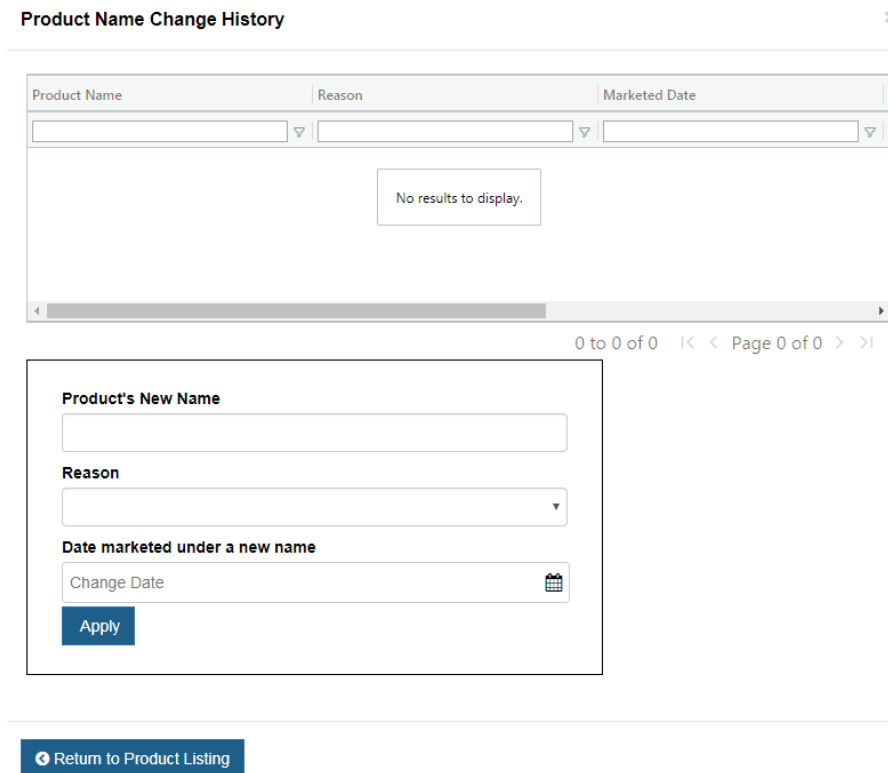

Figure 43

3. Type in the product's new name.

   NOTE: If you change the ingredient or recipe of your product, it would be considered a NEW product, and NOT a product name change.

4. Pick a reason for the product name change.

5. Select the marketing start date for the new name.

   NOTE: You cannot pick a future date. Once the product name is changed the step 8 tab will turn red. You will need to review if material file association(s) and/or material file(s) need to be updated.

Product Information

1. Once your product has been submitted and assigned a tobacco product

(TP) number, you will not be able to change the TP number or product name.

2. You can make changes to the other fields/columns that are not grayed out on the table grid.

3. You can also add a comment or update the product's name by clicking the appropriate action icon.

To Add a Product

1. From your registration, go to Step 5: Products.

2. Select one of the options available to add your product(s).

3. Enter all the necessary information about the product.

    NOTE: The "Marketing Status Change Date" and "Marketing Status" MUST be completed for the system to accept the added product.

Product Status

To individually update a product status, please follow the steps below:

4. From your registration, go to Step 5: Products.

5. Find your product.

6. Scroll to the far-right of the table grid until you see the "Marketing Status" column.

7. Select "Discontinued" from the drop-down menu.

8. Once selected, the product status will automatically change from "Active" to "Inactive."

9. Select "Reintroduced to Market" to change the product status from "Inactive" to "Active."

To do a bulk product update, please follow the steps below:

1. From your registration, go to Step 5: Products.

2. Click on the "Bulk Product Update" button on the bottom of the table grid (see Figure 44).

Action	TP Number	Product Status	Product Name
👁💬🕘	TPBMJVC74	Inactive	Test Product 1.2
👁💬🕘	TPBMJVC75	Active	Test Product 2
👁💬🕘	TPBMJVC76	Active	Test Product 3
👁💬🕘	TPBMJVC77	Active	Test Product 4
👁💬🕘	TPBMJVC78	Active	Test Product 5

Bulk Product Update

Figure 44

3. The Bulk Product Update window will be displayed (see Figure 45).

Bulk Product Update

You can change the product/marketing status of multiple product listings at the same time using Bulk Update.

a. Using the Product Status radio buttons, select Active if you want to inactivate Active products or select Inactive if you want to activate Inactive products.
b. Filter the products you want to update by using the filters on the TP Number, Product Name and Product Identification Number.
c. Using the checkboxes, select the products for which you want to change the marketing status.
d. Enter the marketing status details in the section below.
e. Click Apply to complete your changes.

Product Status: ⦿ Active ◯ Inactive

Select All | Unselect All

Select	TP Number	Product Name	Product Identification Number
☐	TPBMJVC75	Test Product 2	
☐	TPBMJVC78	Test Product 5	
☐	TPBMJVC77	Test Product 4	
☐	TPBMJVC76	Test Product 3	

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| Change Marketing Status | | Reason For Change | |
| Marketing Status Change Date | Change Date | | |

◀ Return to Product Listings   ❯ Apply

Figure 45

4. You can individually select the products or use the buttons at the top of the table grid (see Figure 45).

5. Follow the directions on the window.

6. Click on the "Return to Product Listing" button or the "X" on the top right-corner to close out of the window.

   NOTE: The product status will automatically be updated by the system once you click on the "Apply" button from the Bulk Product Update window.

8. Change Log

Starting on October 29, 2018, the system will capture the changes made to your registration and product listing, including your material files.

You can access the Change Log by going to the Menu option and clicking on the Change Log section of the menu (see Figure 46).
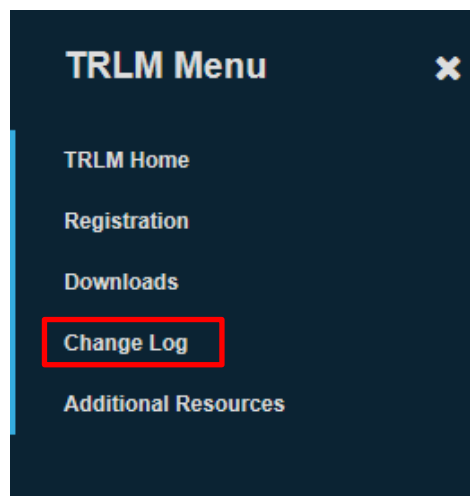
Figure 46

You can review the information on the screen, as well as filter for a specific information using the search boxes above the columns (see Figure 44).
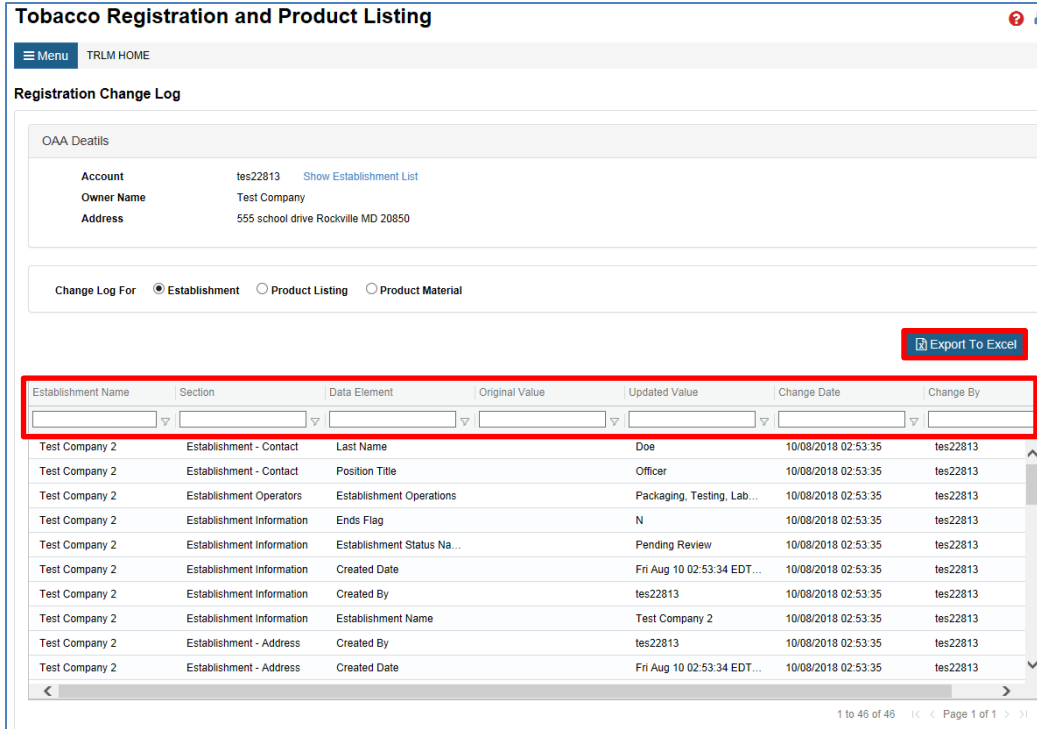
Figure 47

NOTE: The change log will only show changes made from October 29, 2018 and onward.

You can also export the log to an Excel file for your records. Click on the Export button above the table grid (see Figure 47).

9. Downloads

This section will allow you to view your generated files.

The system typically autogenerates most of the requested files (either Excel or PDF). However, some file requests may need to be processed offline due to the volume of information. If your file needs to be processed offline, a message will appear on your screen and an email will be sent to you once the file is available.

To access your files, go to the "Downloads" section from the TRLM Menu options (see Figure 48).
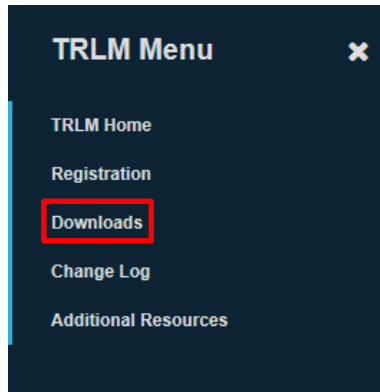
Figure 48

A list of files will be shown (see Figure 49). These files will be available to you for the next 30-days.
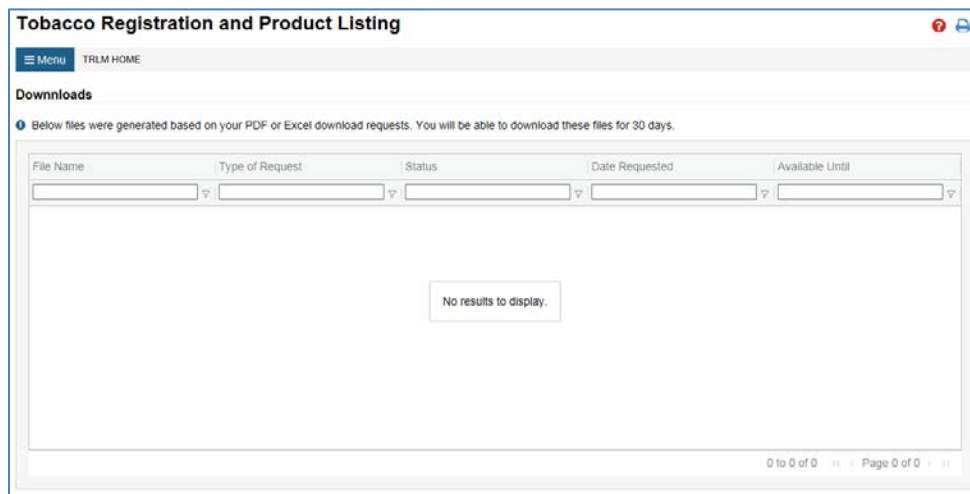
Figure 49

APPENDIX

Product Listing Infographic

Step 5: Product Listing Registration

1 Navigation

At the top of the page are navigational tabs for each step of the Tobacco Registration and Product Listing process. A green tab with a check mark indicates that step is complete. A blue tab with the text "in progress" indicates that step is currently active. A red tab with an "X" means that step is incomplete. A gray tab is not available either because that information is not needed, or because other steps need to be completed first. You can click on the available tabs to go to previous steps as you work through your product listing.
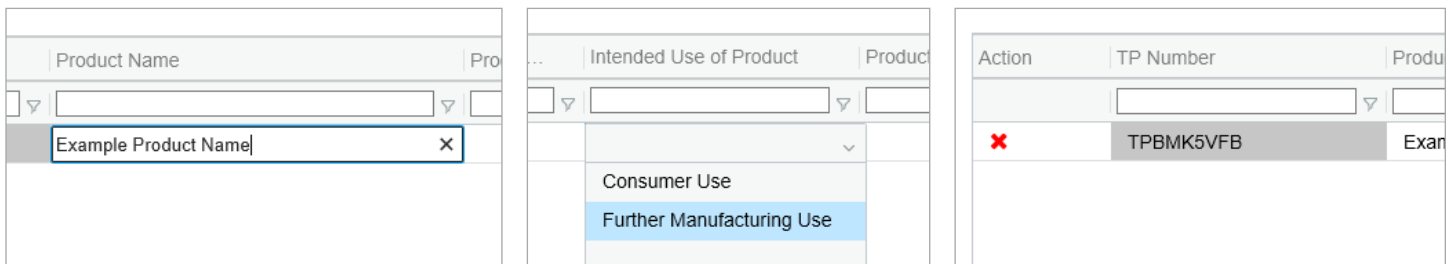
2 Adding Product Listings

There are three methods to add product listings to the table: add the listing individually, copy and paste listings from a spreadsheet, or upload a spreadsheet of the listings.

Adding Product Listings Individually

To add a listing individually, click the "Add Product" button above the table. This will create a new blank row in the table. In a new product listing, the "TP Number" will be blank and uneditable.

Add the product listing information by clicking on each data cell in the row, or by tabbing through. Some data cells are selections utilizing a drop down like "Intended Use of Product." Double-click on the data cell, or tab to the cell and press "enter," to open the drop down. When a product listing has the required information the "TP Number" will auto-populate.

Copy Product Listings from a Spreadsheet

Make sure the column order in the spreadsheet matches the TRLM table. Click the "Add Product" button to add a new row to the table. Copy up to 100 rows from the spreadsheet, select the Product Name cell, then paste. Add additional listings in the same manner.

Upload a Spreadsheet of Product Listings

Download the Product Listing Template. You can upload a maximum of 250,000 product listing per spreadsheet, with a maximum file size of 50MB. For additional listings, upload multiple spreadsheets. Click the "To upload an Excel spreadsheet containing your product listing;" button, then click on the hyperlink in step four.

⚠ Please update the below fields for the selected row.

- Intended Use of Product is required.
- Product Category is required.

✓ *Success:* Record Saved

Messages

Red error messages will appear above the table if a product listing has an error or is missing required information. When the product listing is successfully added, a green "Success" message will display above the table.

3 Actions

✖ Click the "X" icon to delete the product listing. Only new product listings can be deleted; once the listing has been submitted it can not be deleted.

⚠ The hazard icon indicates there are errors within the row. Double click the icon to display the error message above the data grid.

The following action icons appear only after the registration is submitted:

👁 Click the view icon to open a pop-up containing additional details about the product listing.

💬 Click the speech bubble to open a pop-up to enter comments and view the comment history.
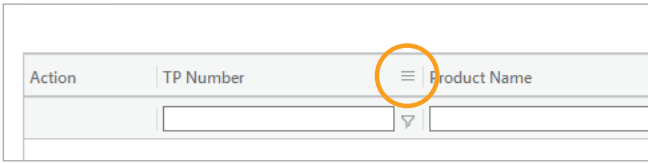
🕓 Click the history icon to open a pop-up to change the product name and view the product name history. Make sure to upload a new product label and associate it to the product after the product name is updated.

After making product name changes and clicking the Save and Continue button, the Step 8 tab will turn red. When on Step 8, if you hover over the Step 8 tab a popover will read "A product name has been updated. Please upload the new product label and associate it to the product."

Step 7: Material File Uploads ✓	Step 8: Material File Association (In Progress)	Step 9: Review ✓

4 Column Controls

Each column in the table has tools that can help you with your product listing. Hover your mouse over the column headers until you see the hamburger (three dashes), then click on the hamburger icon to open the column options.
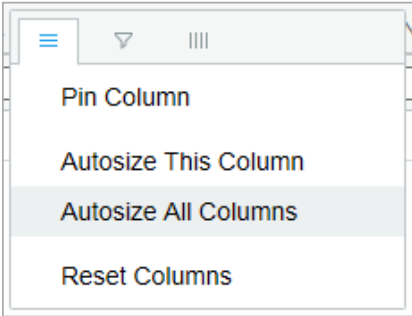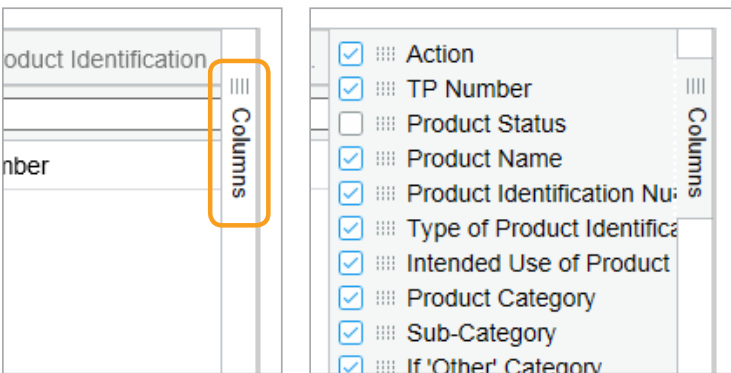

Pin Column moves the selected column to its immediate left or right.

Autosize This Column expands the *selected* column to display all of the character values within the column.

Autosize All Columns expands *all* columns to display all of the character values within the columns.

Reset Columns resets the column display to its original (default) state.


On the right side of the table is the **Columns** tab which opens a side panel of all available columns, and allows you to select which columns are displayed in the table. Checked columns will be displayed in the table. To hide the side panel, click the **Columns** tab again.

5 Sorting, Filtering, and Searching
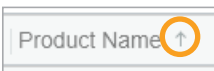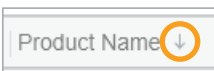
You can sort your information in ascending or descending order for any column.
Click anywhere in the column header to sort by descending order (represented by an arrow pointing down). Click the column header again to sort in ascending order (arrow pointing up). Click a third time to dismiss the sorting.
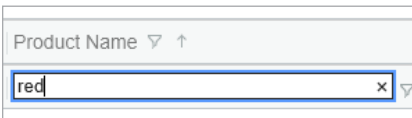
You can filter the product listings for specific information within a column by typing directly into the form field below the column header to filter for information. Please avoid using non-alphanumeric characters including spaces.

The table displays 100 rows/listings at a time. The pagination below the table allows you to navigate by groups of 100 listings. You can also enter the page number in the text box to skip to a certain page.