



U.S. Food and Drug Administration

Center for Tobacco Products (CTP)

**Product Form Validator Tool
User Guide**

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1 Introduction

This user guide provides an overview of the **Product Form Validator Tool** that was developed for the Office of Science (OS) at the Center for Tobacco Products (CTP). The Product Form Validator Tool allows applicants to validate data in **Unique Identifying Information for New Tobacco Products** forms prior to submission.

Benefits of the Product Form Validator Tool include:

- A **simple** and **easy-to-follow** design
- **Quick** and **efficient** data validation processing
- Detailed output that informs applicants of form errors and omissions **prior to submission**
- **Reduces time** spent in review, correction, and resubmission

For background, the FDA CTP requires that a Premarket Tobacco Product Application (PMTA) includes scientific data that demonstrates a product is appropriate with regards to the protection of public health. Specifically, the application being submitted must include this data in *Form FDA 4057b – PMTA Unique Identifying Information for New Tobacco Products*.

Additionally, as of February 15, 2007, the FDA CTP requires that a Substantial Equivalence (SE) submission includes demonstration that a new product is substantially equivalent to a pre-existing product on the market. The SE standard requires showing that any product characteristics not identical to the pre-existing predicate product do not raise different questions of public health. Specifically, the SE submission must include this information in *Form FDA 3956b - SE Unique Identifying Information for New Tobacco Products*.

2 Start Here: Frequently Asked Questions

- **Are applicants required to use the Product Form Validator Tool?**
No. Use of the tool is optional although it is highly recommended.
- **What specific forms can the Product Form Validator Tool validate?**
 - Form FDA 4057b - PMTA Unique Identifying Information for New Tobacco Products (v3.1)
 - Form FDA 3956b - SE Unique Identifying Information for New Tobacco Products (v1.0)
- **What are the system requirements for the Product Form Validator Tool?**
 - Windows (64-bit version)
 - Java 17
 - 100 MB of disk space
 - Microsoft Excel
 - Adobe Acrobat Reader
- **Does the Product Form Validator Tool work with assistive technology?**
Yes. JAWS, Job Access With Speech, is the recommended screen reader. For Windows Vista or later versions of Windows, you must enable the Java Access Bridge. For related instructions, refer to the [Part 4 - Enable Java Access Bridge](#) topic.
- **Is it OK to have more than one version of Java installed? For example, if another application requires a different version of Java.**
As long as Java 17 is installed and the JAVA_HOME environment variable points to the applicable Java 17 folder, it's OK to have another version of Java installed. For related information, refer to the [Part 3 - Configure JAVA_HOME Environment Variable](#) topic.

3 Downloading, Installing & Configuring Software

This topic includes five sections that provide details on downloading, installing, and configuring applicable software and related settings needed to use the Product Form Validator Tool.

- Part 1 - Download & Install Java 17
- Part 2 - Verify Java 17 Installation
- Part 3 - Configure JAVA_HOME Environment Variable
- Part 4 - Enable Java Access Bridge
- Part 5 - Download & Extract Product Form Validator Tool

Part 1 - Download & Install Java 17

1. Navigate to the [Java Downloads for Windows](#) page on Oracle.com.
2. Download the applicable Java 17 installer file for Windows 64-bit.
3. Run the downloaded installer file and follow the on-screen instructions to complete the install.

Part 2 - Verify Java 17 Installation

1. Type **cmd** in the Windows search bar and press **Enter**. This will open a Command Prompt window where you can verify that the Java 17 install was successful.



Figure 1: Windows search bar - cmd

2. Type **java -version** at the prompt and press **Enter**.

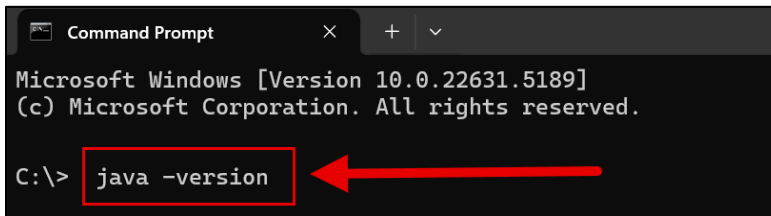


Figure 2: Java -version command

3. View the output to confirm whether Java 17 is installed. (NOTE: The specific Java 17 release numbers may vary.)

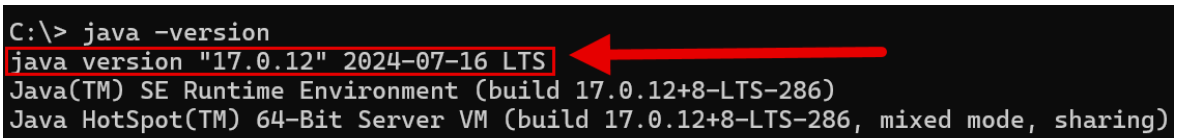


Figure 3: Java -version output

Part 3 - Configure JAVA_HOME Environment Variable

Perform the following steps to configure the JAVA_HOME environment variable to point to the Java 17 folder on your computer.

1. Type **System Variables** in the Windows search bar and press **Enter**.



Figure 4: Windows search bar – system variables

2. Select the **Environment Variables** button.

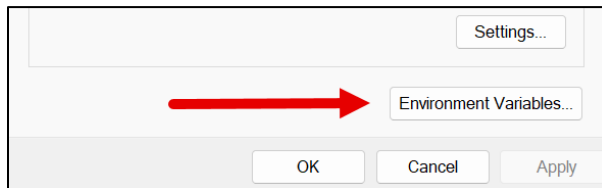


Figure 5: Environment Variables button

3. Select the **New** button below the **System Variables** section.

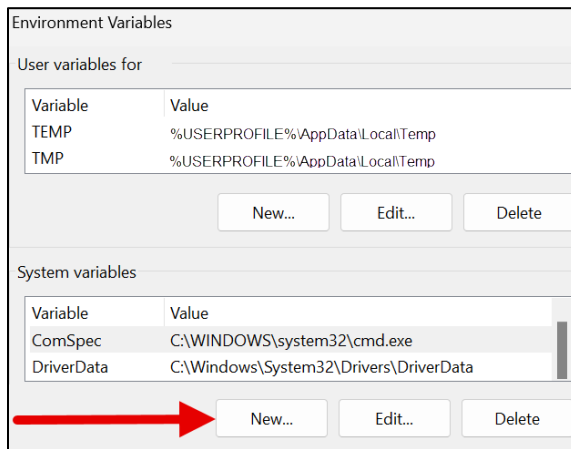


Figure 6: New button to enter system variable

4. Type **JAVA_HOME** in the “Variable name” box. Then, to populate the “Variable value” box, select the **Browse Directory** button and navigate to the applicable Java 17 folder.

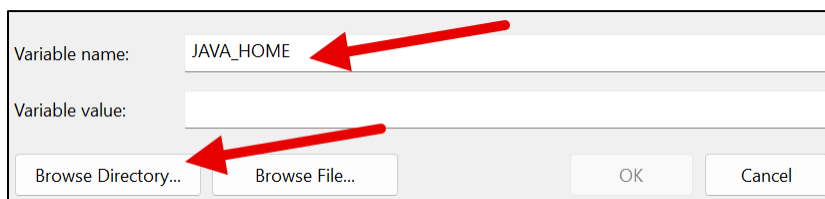


Figure 7: Variable name and Variable value system variables

5. Select the **OK** button.

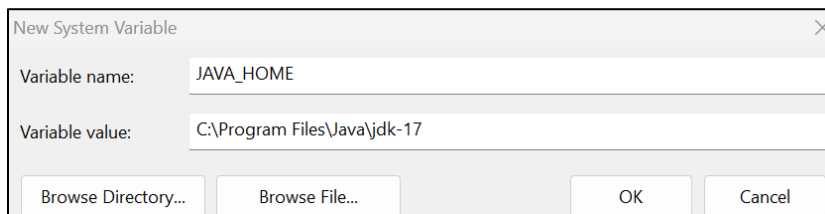


Figure 8: Populated Variable name and Variable value system variables

Part 4 - Enable Java Access Bridge

If you would like to use a screen reader with the Product Form Validator Tool, you must first enable the **Enable Java Access Bridge** option within the operating system's Ease of Access Center. This requirement is applicable starting with Windows Vista and later versions.

1. Type **Control Panel** in the Windows search bar and press **Enter**.



Figure 9: Windows search bar – Control Panel

2. Select the **Ease of Access** link.

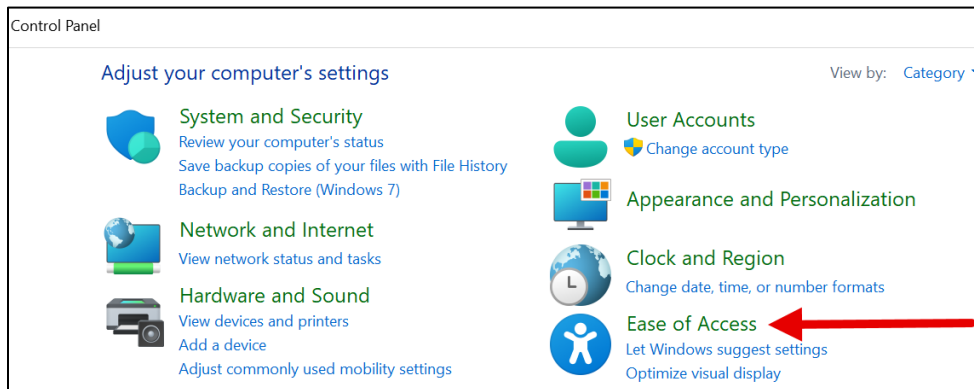


Figure 10: Ease of Access link

3. Select the **Ease of Access Center** link.

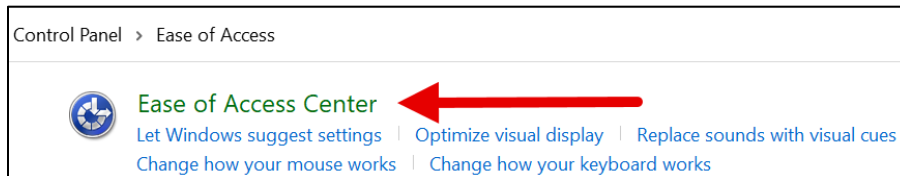


Figure 11: Ease of Access Center link

4. Select the **Use the computer without a display** link.

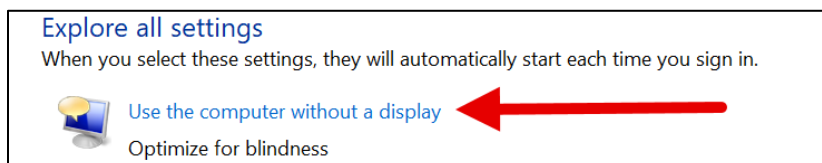


Figure 12: Use the computer without a display

5. Select the **Enable Java Access Bridge** checkbox in the “Other programs installed” section.

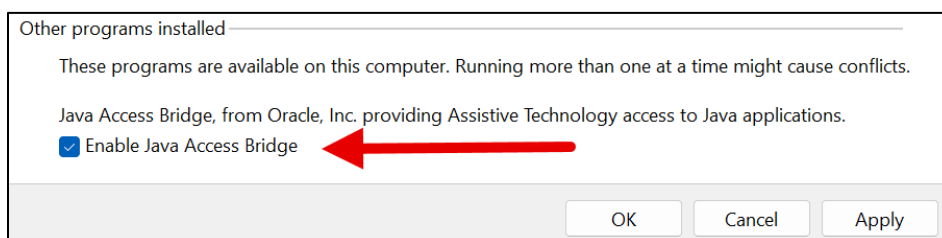


Figure 13: Enable Java Access Bridge

6. Select the **OK** button.

Part 5 - Download & Extract Product Form Validator Tool

To obtain the Product Form Validator Tool, you will simply need to download the Product_Form_Validator_Tool_v2.zip file as described below. Once you extract the downloaded .zip file, you can immediately start using the tool.

1. Select the [Download Product Form Validator Tool Software](#) link to download the Product_Form_Validator_Tool_v2.zip file from FDA.gov.
2. Navigate to the downloaded **Product_Form_Validator_Tool_v2.zip** file. Then select the **Extract All** option on the tool bar.

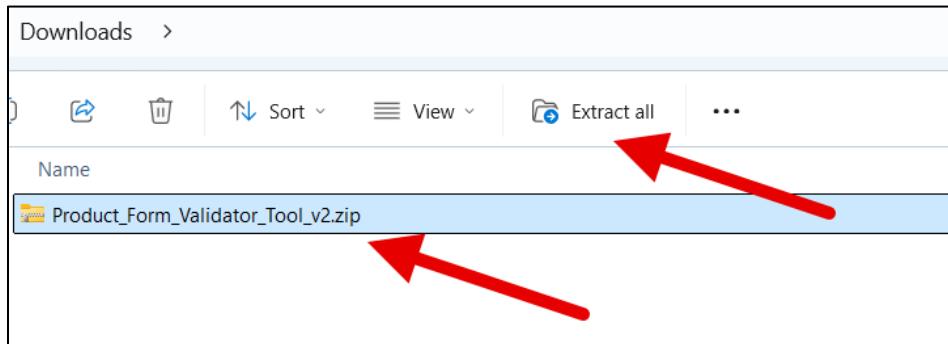


Figure 14: Menu option to extract Product_Form_Validator_Tool.zip content

3. Select the **Browse** button to select where to save the Product Form Validator Tool v2.exe file (or accept the default path).
4. Select the **Extract** button.

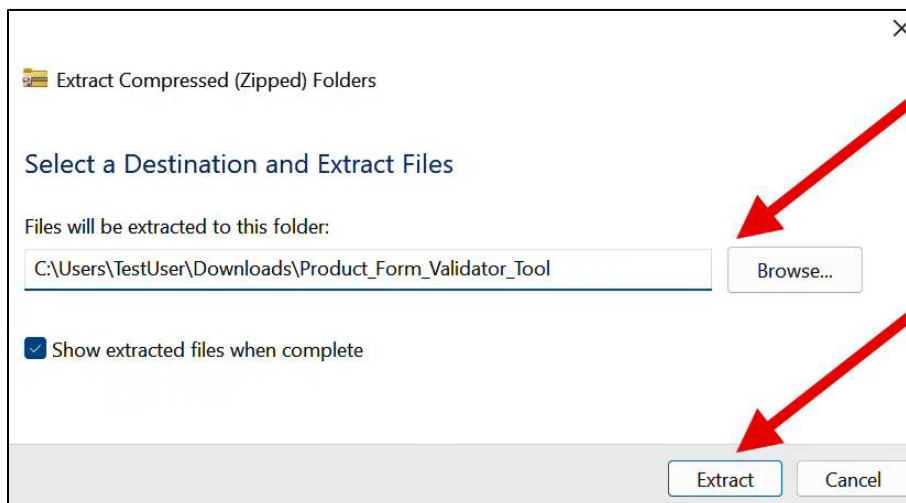


Figure 15: Browse & Extract buttons

4 Using the Product Form Validator Tool

This section includes step-by-step instructions for how to use the Product Form Validator Tool to validate Unique Identifying Information for New Tobacco Products forms.

IMPORTANT: Note the following before attempting to validate a form:

- The tool can validate only one form at a time
- The form cannot be open during validation
- The form must have either an .xls or .xlsx file type extension
- The form must be one of the following form types and versions (or later):
 - Form FDA 4057b - PMTA Unique Identifying Information for New Tobacco Products (v3.1)
 - Form FDA 3956b - SE Unique Identifying Information for New Tobacco Products (v1.0)

Part 1 - Attempt to Validate a Form

1. Launch the **Product Form Validator Tool** (*Product Form Validator Tool v2.exe*).
2. Select the **Choose File** button.



Figure 16: Choose File button

3. Navigate to the applicable form and select the **Open** button.

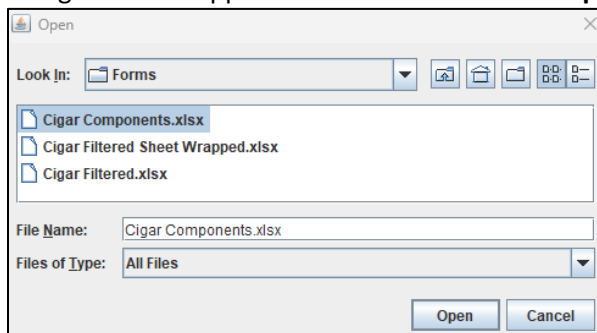


Figure 17: Example folder containing completed forms

4. Select the **Validate File** button.

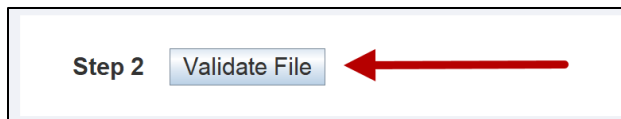


Figure 18: Validate File button

5. View the **Validated Completed** pop-up box:
 - If it shows **Validation Successful**, select the **OK** button, and then skip to the [Part 3 - Generate Completion Certificate](#) topic.
 - If it shows **Validation Failed**, select the **OK** button, and then proceed to the [Part 2 - Generate Issue Report & Correct Issues](#) topic.

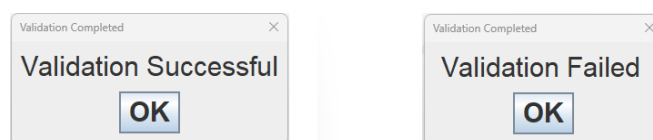


Figure 19: Validation Successful and Validation Failed pop-up boxes

Part 2 - Generate Issue Report & Correct Issues

When a form fails validation, an Issue Report button will appear on screen. Perform the steps described below to generate an Issue Report to review. The report contains a copy of data from each row that failed validation. Additionally, the following three columns appear in the report with helpful information: (1) column ED - Original data row #, (2) column EE - Status, and (3) column EF - Error message.

1. Select the **Issue Report** button.

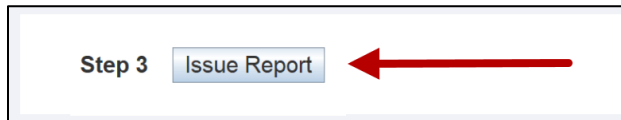


Figure 20: Issue Report button

2. Select the folder where you want to save the report. Then select the **Save** button.

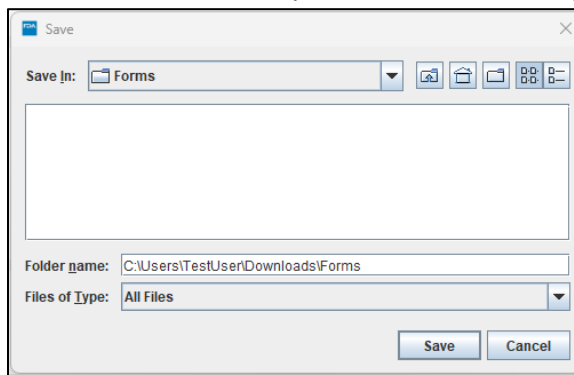


Figure 21: Example folder for Issue Reports

3. Navigate to and open the saved report. The file name for the report will reflect the form's name with "**_Errors**" added to it. See the example below.

"Cigar Filtered_**Errors**.xls" will be the Issue Report's file name for "Cigar Filtered.xls"

4. Scroll right to the last three columns to review the following data for each row: column ED - Original data row #, column EE - Status, and column EF - Error message.

	AQ	BG	BH	BI	BJ	ED	EE	EF
	Nicotine Source	Additional Properties (if Applicable)	Dates When Commercially Marketed in US Has this ever been marketed in the US?	Dates When Commercially Marketed in US 1st commercial market date	Dates When Commercially Marketed in US Is product currently marketed in the US?	Original Data Row#	Status	Error Message
	Non-Tobacco		No			6	Validation Error	Characterizing Flavor, If Flavored (Column O): If "Characterizing Flavor" is Flavored, then "Characterizing Flavor, If Flavored" must have an entry. If you do not have values for a field, you must leave the cell blank. Please refer to the Premarket Tobacco Product Applications and Record Keeping Requirements rule for the required properties based on product category and subcategory.
	Tobacco					7	Validation Error	Has this ever been marketed in the US? (Column BH): "Has this ever been marketed in the US?" is a required field for product.
			Yes			9	Validation Error	Package Type (Column F): "Package Type" is a required field for product. 1st commercial market date (mm/dd/yyyy) (Column BI): The "1st commercial market date (mm/dd/yyyy)" is required when answering "Yes" if the product was previously marketed.

Figure 22: Sample of an Issue Report

5. Re-open the form that failed validation and make all necessary corrections.
6. Once you have saved and closed the corrected form, repeat the steps in the [Part 1 – Attempt to Validate a Form](#) topic.

Part 3 - Generate Completion Certificate

When a form passes validation, a Completion Certificate button will appear on screen. Perform the steps below to generate a completion certificate that indicates the form passed validation. Be sure to include the certificate along with the application submission. To view samples of a completion certificate, refer to [Appendix A - Completion Certificates](#).

Note the following:

- It is important to generate and save a completion certificate for a successfully validated form **prior to** selecting another form to validate.
- Once you select the “Choose File” button, and then select another form, you can no longer generate or save the completion certificate for the previous form validated during that session.

1. Select the **Completion Certificate** button.

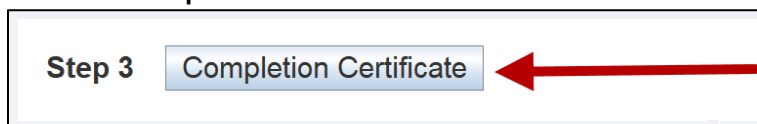


Figure 23: Completion Certificate button

2. Navigate to the location to save the certificate. Then select the **Save** button.

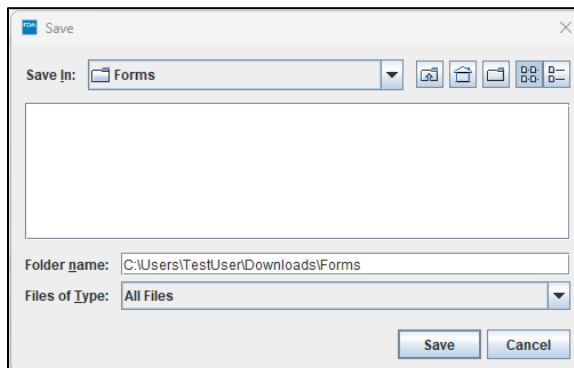


Figure 24: Example folder for completion certificates

3. Navigate to and open the certificate to view it. The file name for the certificate will reflect the form's name with “**_Certificate**” added to it. See the example below.

“Cigar Filtered_**Certificate**.pdf” will be the certificate's file name for “Cigar Filtered.xls”

5 Appendix A - Completion Certificates

See below for sample completion certificates for successfully validated Unique Identifying Information for New Tobacco Products forms.

Certificate of FDA Form 4057b Validation

THIS ACKNOWLEDGES THAT

Test User

Successful Validation: May 14, 2025, 2:11:15 PM

FDA 4057b Pre-Market Tobacco Product Application Product Grouping Spreadsheet

File Name: FDA 4057b ProductGrouping_v3.1_UATBadData_Errors.xlsx
Product Category: Cigars
Subcategory: Cigar Tobacco Filler
Total Products: 1

Validator Version: 2.0
Spreadsheet Version: 3.1

May 14, 2025

If you modify form 4057b after this validation May 14, 2025, 2:11:15 PM, you should complete an additional validation

Successful validation does not mean your application contains all elements required for acceptance of your application per 21 CFR 1105.10 and 21 CFR 1114.5

Figure 25: Completion certificate - PMTA Unique Identifying Information for New Tobacco Products form

Certificate of Form 3965b Validation

THIS ACKNOWLEDGES THAT

Test User

Successful Validation: May 15, 2025, 11:21:58 AM

Form 3965b Tobacco Substantial Equivalence Product Grouping Spreadsheet

File Name: FDA 3965b ProductGrouping_v1.0_UAT.xlsx
Product Category: Cigars
Subcategory: Cigar Tobacco Filler
Total Products: 2

Validator Version: 2.0
Spreadsheet Version: 1.0

May 15, 2025

If you modify form 3965b after this validation May 15, 2025, 11:21:58 AM, you should complete an additional validation

Successful validation does not mean your application contains all elements required for acceptance of your application per 21 CFR 1105.10 and 21 CFR 1114.5

Figure 26: Completion certificate - SE Unique Identifying Information for New Tobacco Products form

6 Appendix B - Troubleshooting Tips

See below for solutions to commonly encountered issues specifically related to using the Product Form Validator Tool.

1. If an “application requires a Java Runtime Environment” error appears when you attempt to launch the tool:
 - You should first verify that Java 17 is installed. Refer to the [Part 2 – Verify Java 17 installation](#) topic for instructions.
 - Next you should add (or recreate) the **JAVA_HOME** environment variable. Be sure to select the **Browse Directory** button to navigate to the applicable Java 17 folder (instead of typing the path). This will ensure that the path is accurate. Refer to the [Part 3 - Configure JAVA_HOME Environment Variable](#) topic for instructions.
 - IMPORTANT: Make sure that you are selecting the **New** button (or, if applicable, the Edit button) that appears in the “System variables” section in the lower portion of the Environment Variables window instead of the one that appears in the “User variables” section in the upper portion of the window.
2. You can prevent most other errors from occurring by noting the following **prior to** attempting to validate a form.
 - The tool can validate only one form at a time
 - The form cannot be open during validation
 - The form must have either an .xls or .xlsx file type extension
 - The form must be one of the following form types and versions (or later):
 - Form FDA 4057b - PMTA Unique Identifying Information for New Tobacco Products (v3.1)
 - Form FDA 3956b - SE Unique Identifying Information for New Tobacco Products (v1.0)
3. If an issue persists with the tool despite implementing the above solutions and tips, collect the following items and send them to the CTP eSub Help Desk at ctpeSub@fda.hhs.gov.
 - A screenshot of the Java 17 folder in Windows Explorer
 - A screenshot of the JAVA_HOME environment variable
 - An Application Log
 - To collect an Application Log, select the “Application Log” link/text that appears in the lower right corner of the Product Form Validator Tool. Then select the “Save to File” button on the output window that appears.