U.S. Food and Drug Administration

Center for Tobacco Products (CTP)

Product Form Validator Tool

User Guide

Document Version Number: 1

September 2023

Table of Contents

List of Figures **0**

1 Introduction **1**

1.1 System Requirements 1

1.2 Installing the Java Development Kit 1

2 Installing and Accessing the Product Validator Tool **4**

2.1 Installing the Product Form Validator Tool (Windows Operating System) 4

2.2 Software Requirements for Assistive Technology 4

2.2.1 Instructions to Enable Java Access Bridge: 4

3 Navigating the Tool **4**

4 How to Use the Product Validator Tool **6**

5 Application Log **13**

List of Figures

Figure 1: Advance System Properties 2

Figure 2: Adding Java Home 3

Figure 3: Product Validator Tool Home Page and Step Guidance 5

Figure 4: Choose File Button 6

Figure 5: File Upload Directory 7

Figure 6: Validate File Button 8

Figure 7: Validation Status Notification - Successful or Unsuccessful 9

Figure 8: Certificate of Completion Example 10

Figure 9: Issue Report Button 11

Figure 10: Issue Report Example® in Excel Format 12
Figure 11: Application Log Button 13
Figure 12: Application Log Results Example 14

1 Introduction

The FDA Center for Tobacco Products (CTP) requires that a Premarket Tobacco Product Application (PMTA) include 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 the form of the "FDA 4057b – Premarket Tobacco Product Application Product Grouping Spreadsheet" (Version 3.0).

The Product Validator Tool can be used to validate the data in your "FDA 4057b – Premarket Tobacco Product Application Grouping Spreadsheet" (Version 3.0) and to check the file for errors or omissions prior to submission; thereby, reducing the time spent in review, correction, and resubmission. While utilizing the tool is not required, it is highly recommended, as it may reduce back-and-forth and save time.

1.1 System Requirements

1. Windows (64-bit system)
2. Java Development Kit (JDK)
3. Microsoft Excel®
4. Adobe® Acrobat Reader
5. 100 MB of disk space

1.2 Installing the Java Development Kit

1. Download the Java 8 JDK installation file - https://www.java.com/en/download/
2. Run the installation
3. Set up the Environmental Variables for Windows
   a. Open **File Explorer** and choose **This PC** to continue. Then right-click it and choose **Properties** from the context menu to continue.
   b. Scroll down and click on "**Advanced System settings**"
   c. Click on the **Advanced Tab** and then click on **Environment Variables**

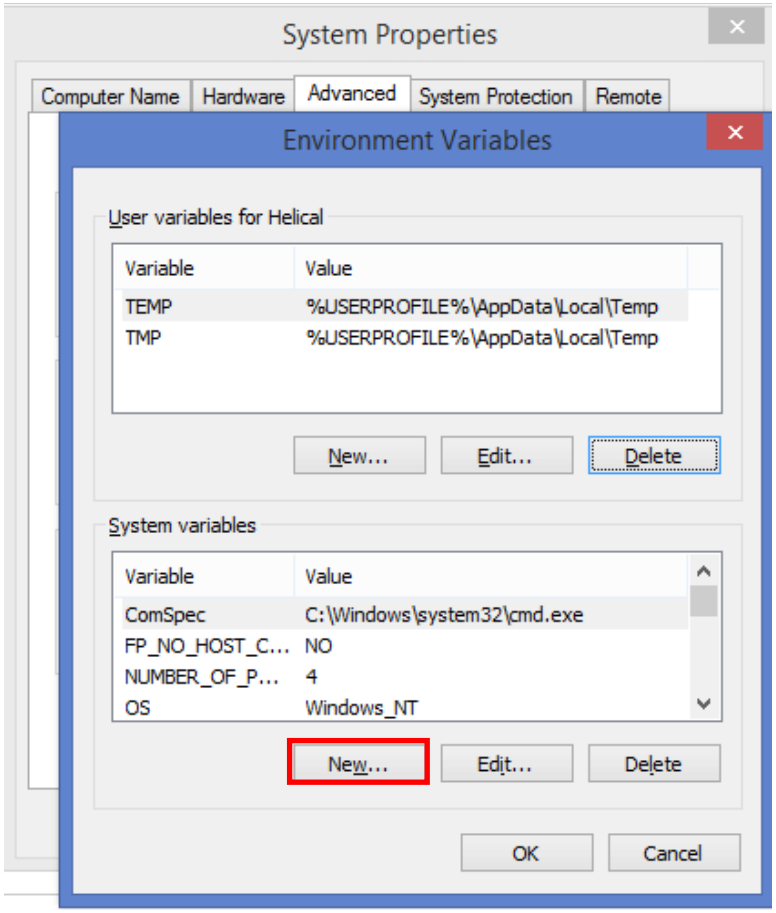


Figure 1: Advance System Properties

4. Click To configure JAVA_HOME by clicking on the **New** button present below System variable section.
5. Add Variable name as **JAVA_HOME** and Variable value as the location of the JDK/java installation directory, **C:\Program Files\Java\jdk<version>** i.e., **C:\Program Files\Java\jdk1.8.0_101.** Your version might have a different number.

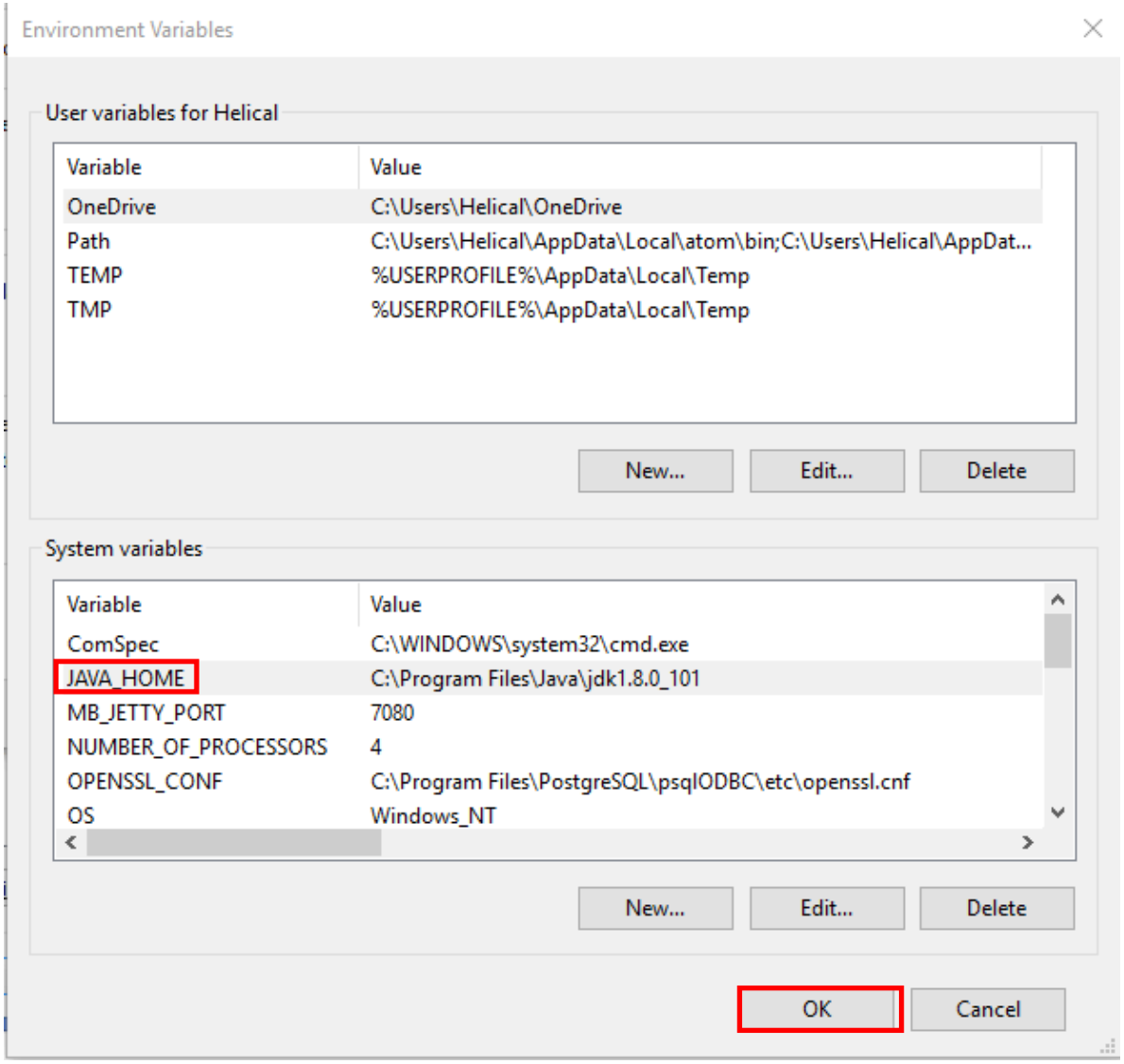


Figure 2: Adding Java Home

6. Save the settings by clicking OK.
7. To check the installation, open the windows command prompt by typing in cmd into the search bar and run the following command: java -version. The command should be understood, and the version number is returned.

2 Installing and Accessing the Product Validator Tool

2.1 Installing the Product Form Validator Tool (Windows Operating System)

1. Navigate to FDA Tobacco Product Application Tips - Premarket Tobacco Product Applications | FDA
2. Select the .zip file for PC.
3. Extract or unzip the exe file for a PC.
4. Double-click on the file to run it and gain immediate access to the Product Validator Tool.

Note: Persons with disabilities having problems accessing the file may call 1-877-CTP-1373 for assistance.

2.2 Software Requirements for Assistive Technology

1. JAWS (Job Access with Speech) is the recommended accessibility tool.
2. For Windows Vista and Later, Enable Java Access Bridge using the steps below in section 2.2.1.

2.2.1 Instructions to Enable Java Access Bridge:

1. Navigate to the Windows **Start** button.
2. Click the **Control Panel** button.
3. Click the **Ease of Access** button.
4. Click the **Ease of Access Center** button.
5. Click the **Use the computer without a display** button.
6. In the section titled **Other programs installed**, select the checkbox next to **Enable Java Access Bridge** (you may have to scroll down).

3 Navigating the Tool

The below describes the various features of the Product Validator Tool:

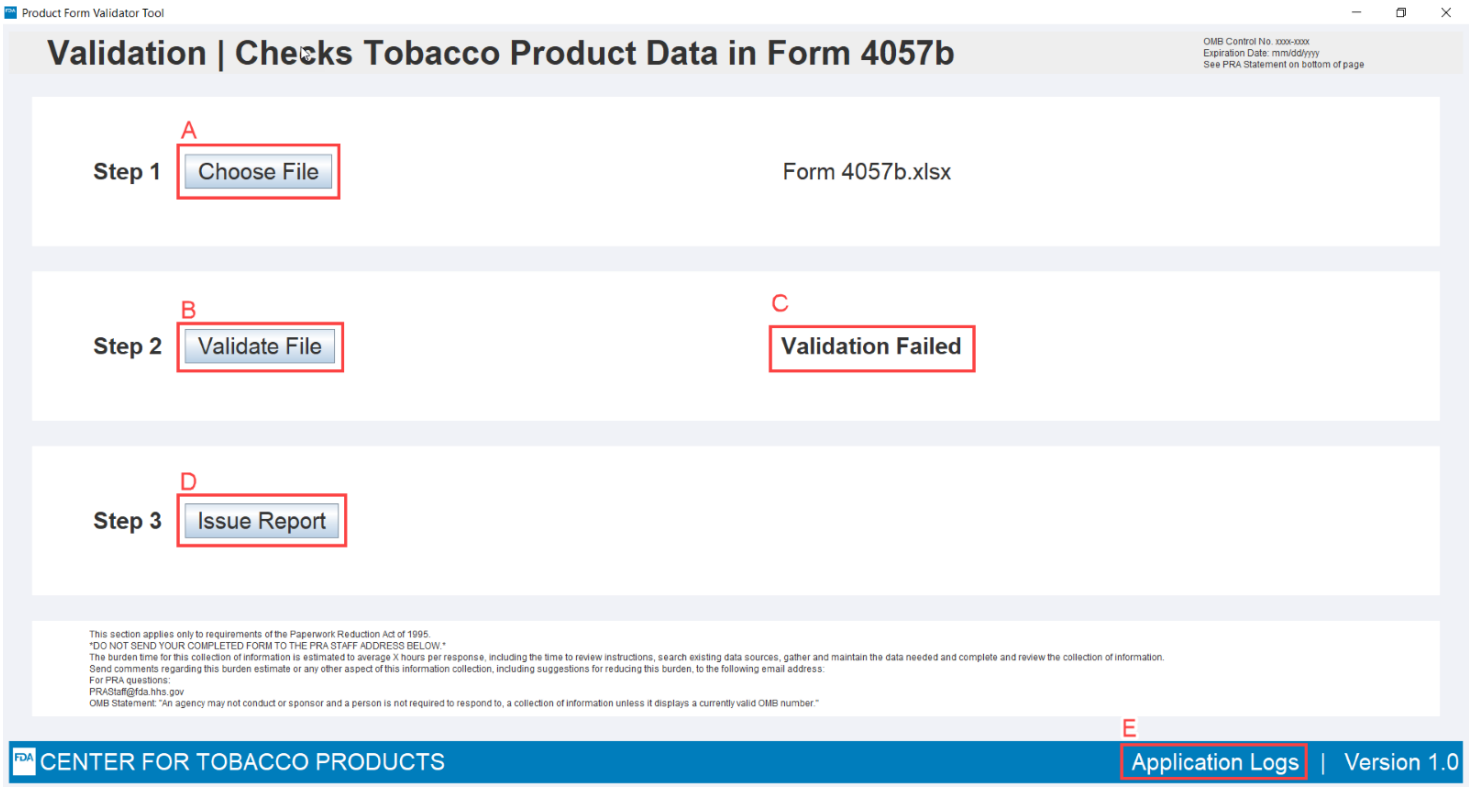


Figure 3: *Product Validator Tool Home Page and Step Guidance*

- **A – Choose File**: Click this button to browse your PC and select the file (Form 4057b Spreadsheet) you'd like to validate.
- **B – Submit File**: Click this button to submit the file for validation.
- **C – Validation Results**: This area displays the validation results (i.e., if your file passed or failed validation).
- **D – Issue Report:** If your file failed validation, click this button to view the errors causing the failure.
- **E - Application Logs:** Refer here if you are troubleshooting issues with the tool and the Help Desk specialist requests these logs.

4 How to Use the Product Validator Tool

This section included step-by-step instructions for how to use the Product Validator Tool to validate a "FDA 4057b – Premarket Tobacco Product Application Product Grouping Spreadsheet" (v3.0) prior to submitting an application.

Please note: Only one file can be validated at a time.

1. Click the **Choose File** button.

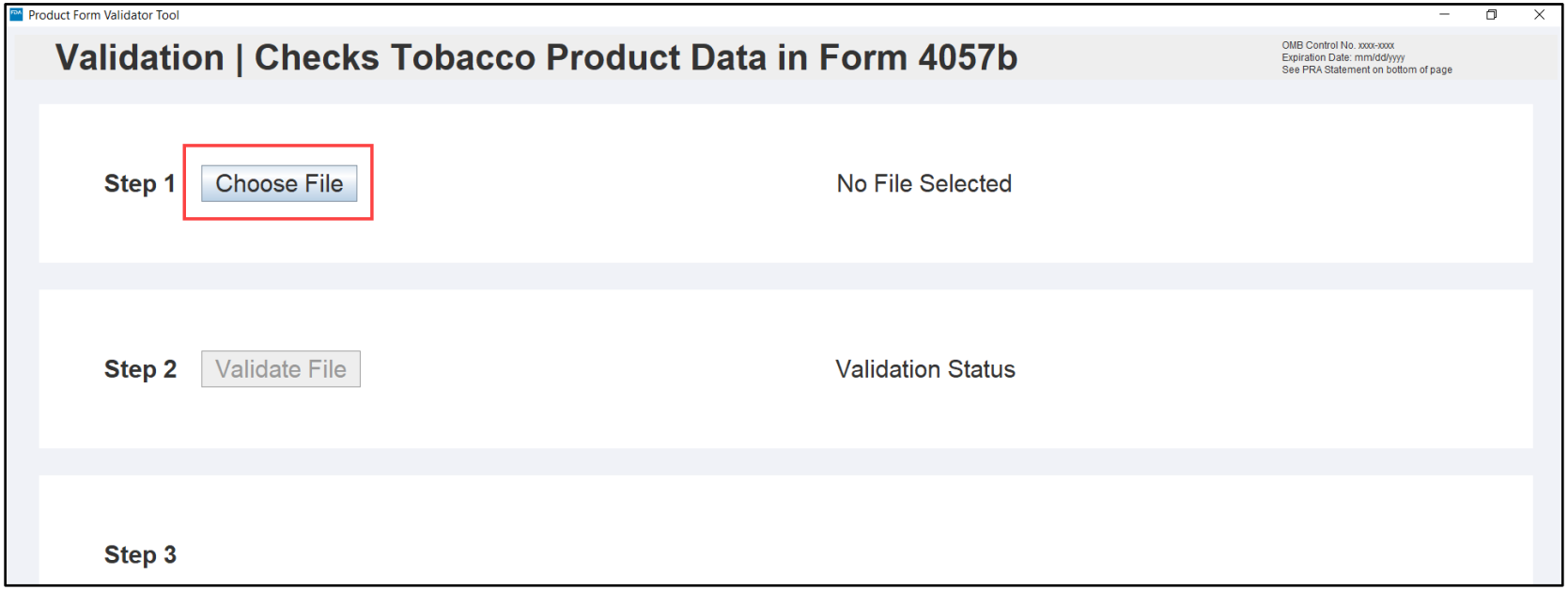


Figure 4: Choose File Button

2. Browse your PC to locate the completed "FDA 4057b – Premarket Tobacco Product Application Product Grouping Spreadsheet" file.
   Note: This file must be in Version 3.0 of the 4057b Product Grouping Spreadsheet with a file extension of .xls or .xlsx.
3. Click the desired file.
4. Click the **Open** button.

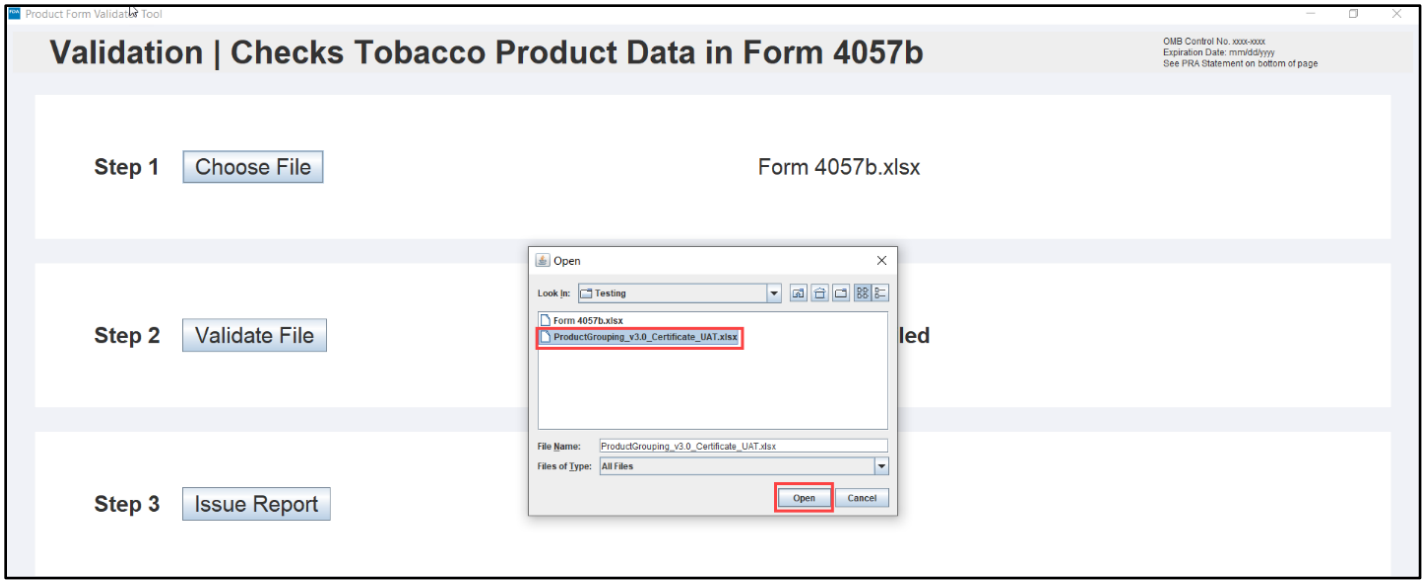


Figure 5: File Upload Directory

5. Click the **Validate File** button.
   Note: The Product Validator Tool will now begin validating the file. A "processing" pop-up will display while the tool processes the uploaded file.

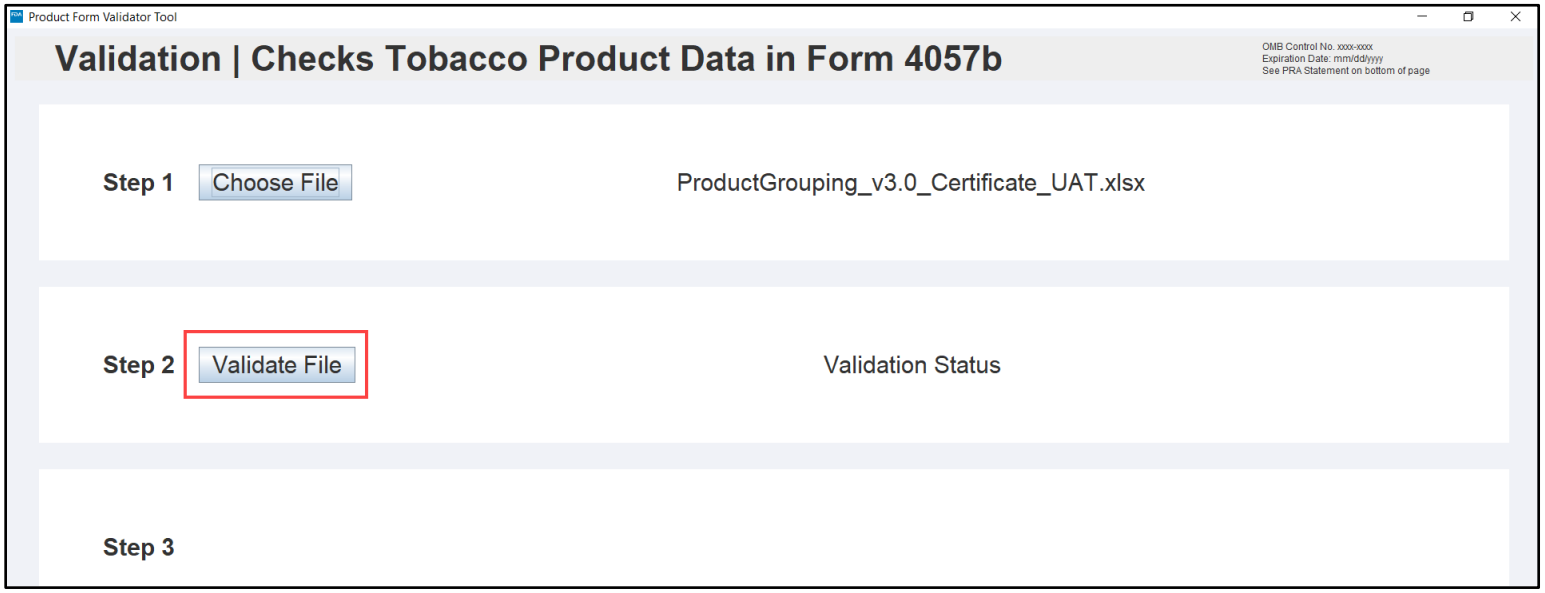


Figure 6: Validate File Button

6. View the **Validation Status**, which indicates that either the file has successfully passed validation or failed validation.

If the Validation Status displays "Validation Successful", please complete steps 7-10 to save the Completion Certificate:

Note: Make sure to save the certificate before validating another file, as choosing a new file will remove the previous file's certificate:

7. Click the **Completion Certificate** button.
   Note: This will save the certificate to a folder on your PC that you designate.

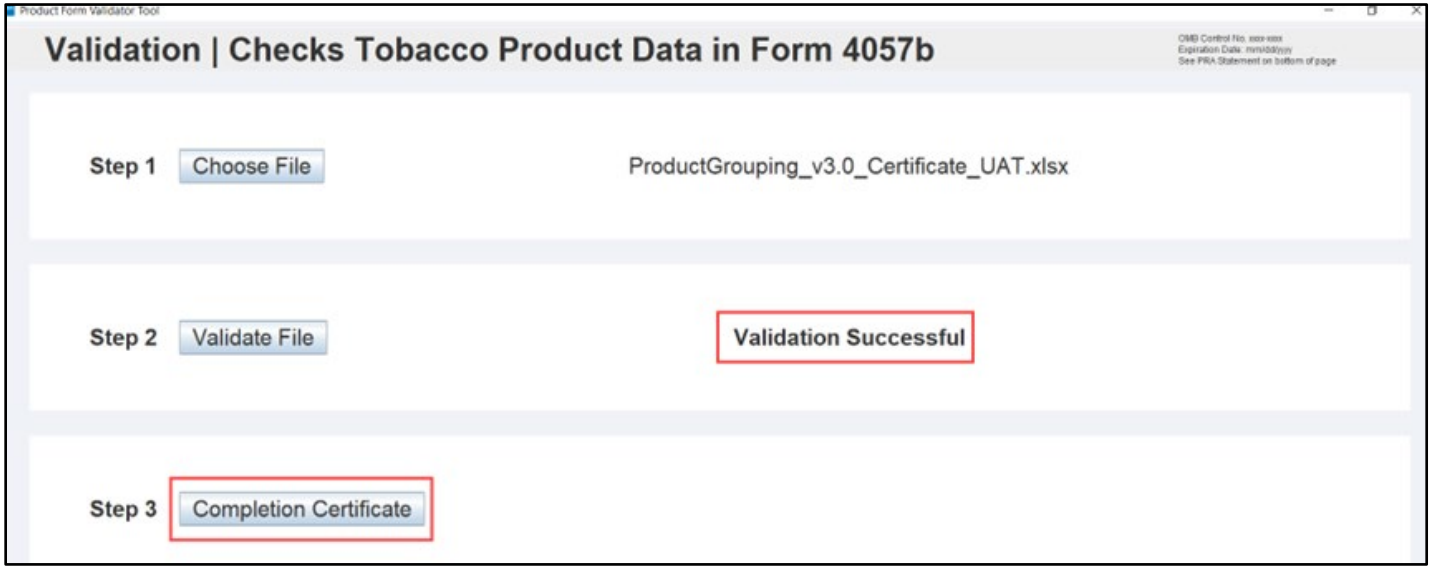


Figure 7: Validation Status Notification - Successful or Unsuccessful

8. Browse and locate the desired folder on your PC where you would like the certificate to be saved.
9. Click the **Save** button.
10. Navigate to the folder and double-click the **Completion Certificate** to open and check the file.

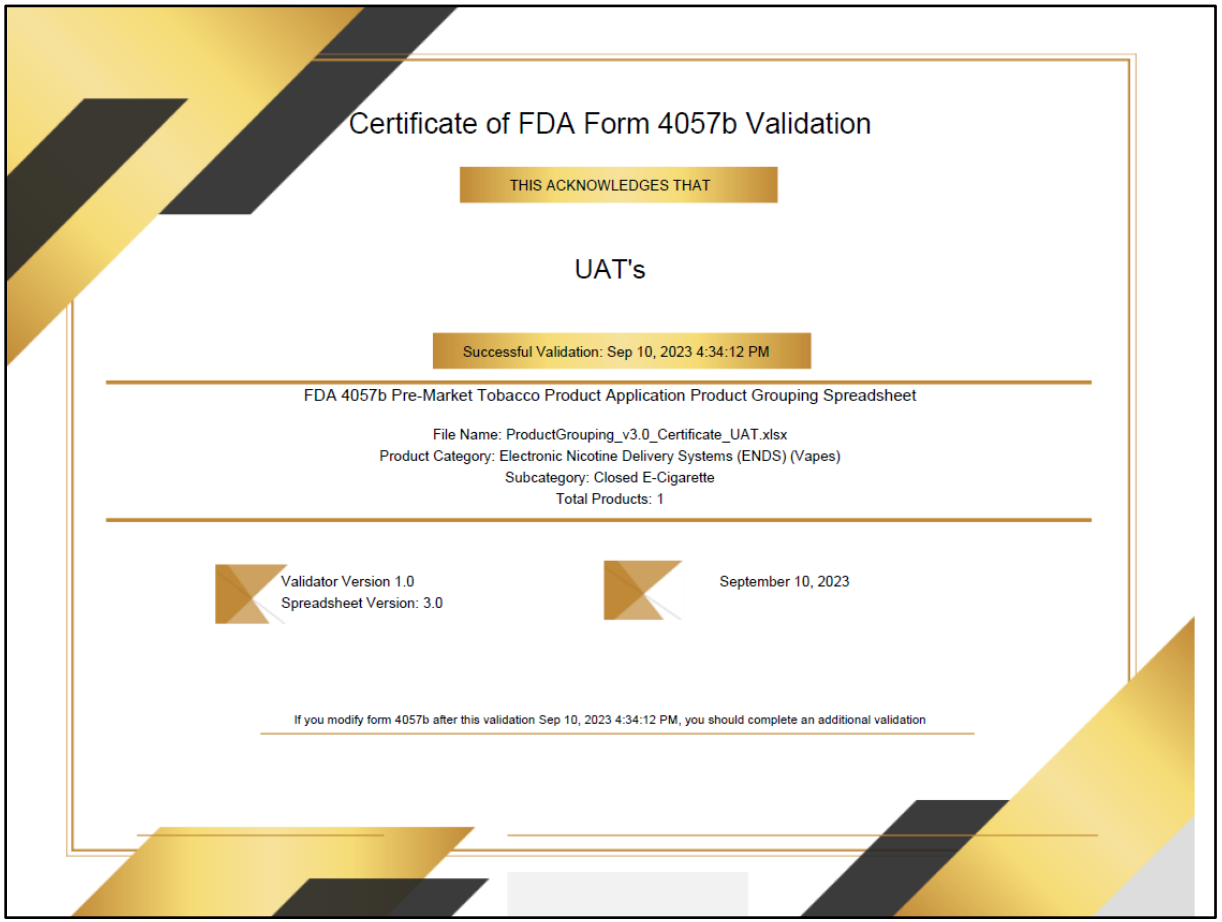


Figure 8: Certificate of Completion Example

Note: You can attach this **Completion Certificate** to your application to the FDA.

If the Validation Status displays "Validation Failed", please complete steps 11-15:

Note: Premarket Tobacco Product Applications and Recordkeeping Requirements Rule identifies the product characteristics that must be provided to accurately submit a file for FDA CTP review. The Issue Report provides descriptions of the product-level data that is required yet missing from the uploaded file.

11. Select the **Issue Report** button.
    Note: This will save the Issue Report to a folder on your PC that you designate.

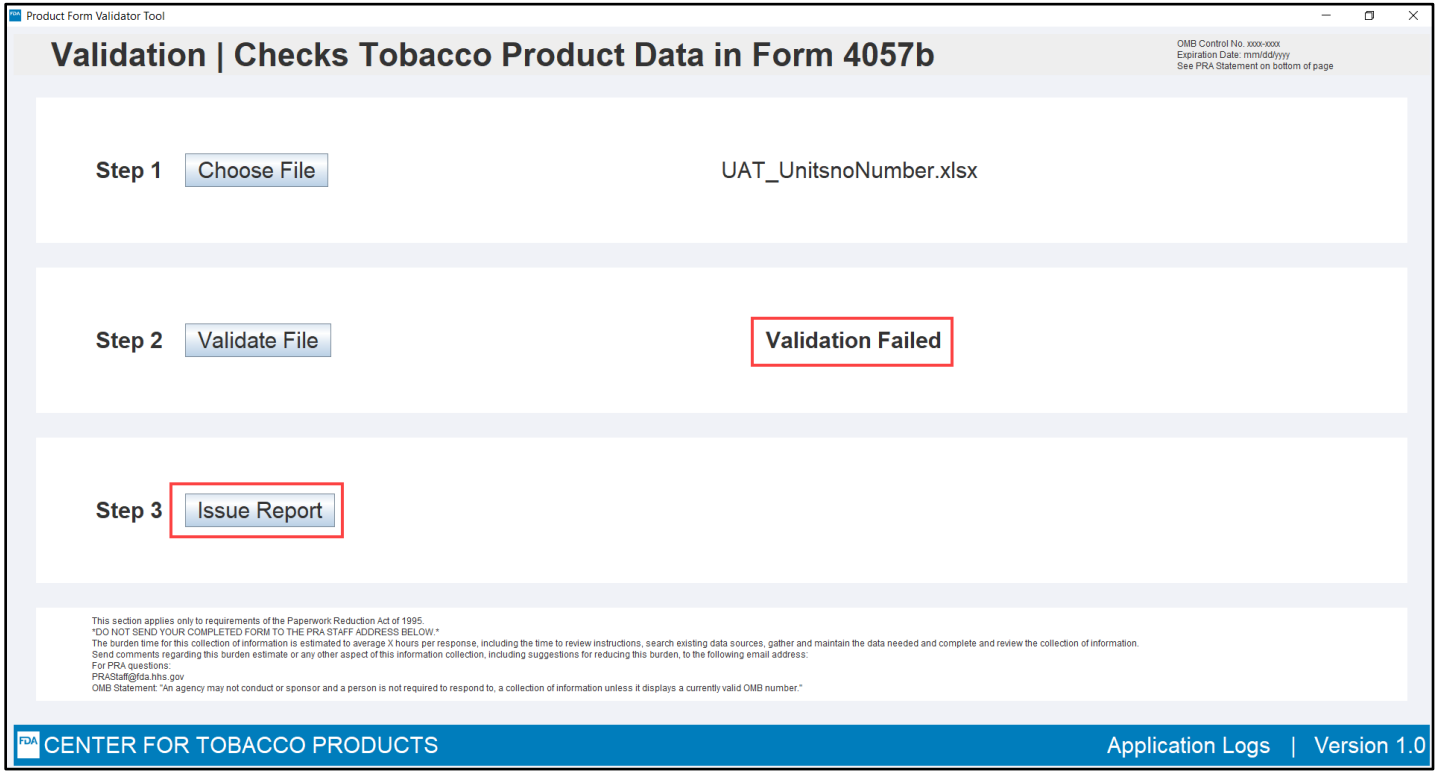
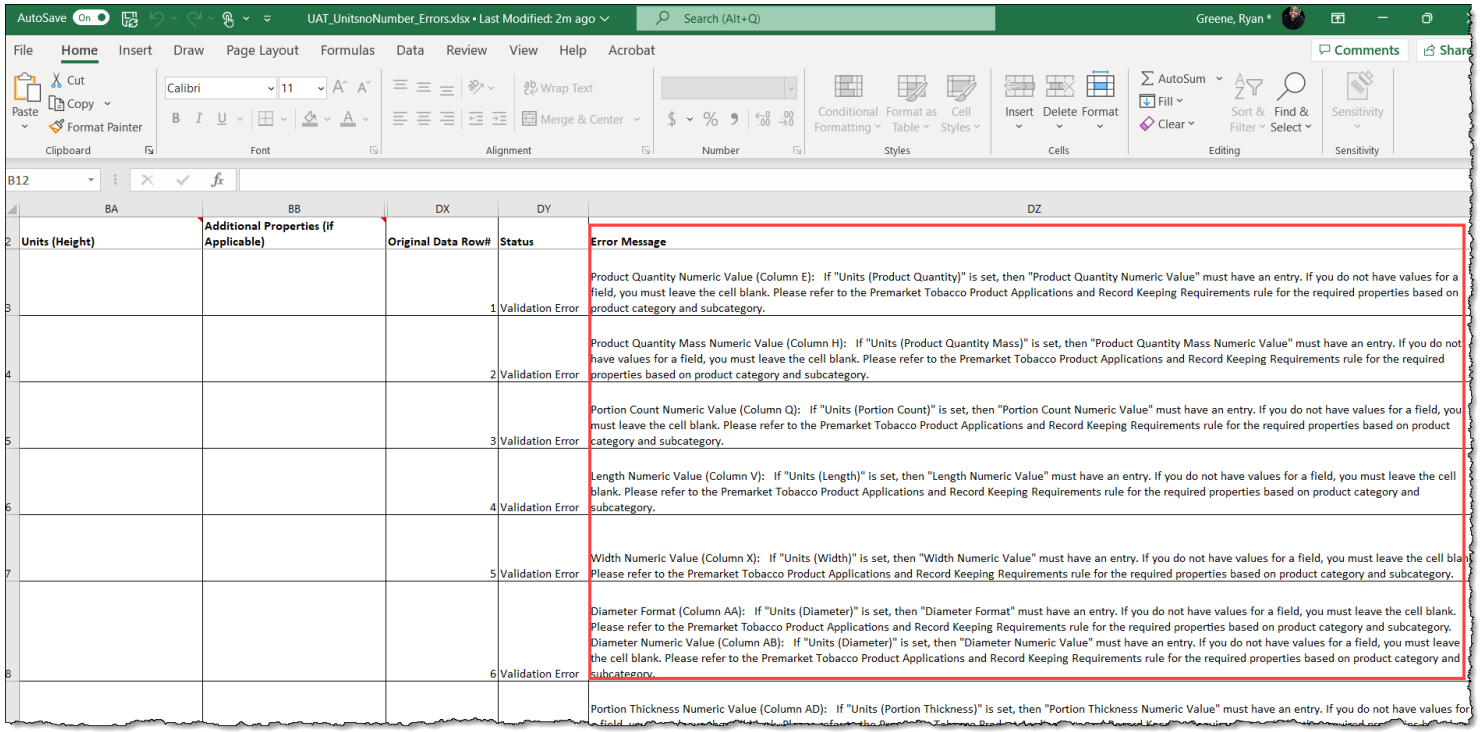


Figure 9: Issue Report Button

12. Browse and locate the desired folder on your PC where you would like the Issue Report to be saved.
13. Click the **Save** button.
14. Navigate to the folder and double-click the **Issue Report** to open the file.
15. Review the Issue Report details, which includes the incorrect or omitted data that caused the file to be rejected.



	BA	BB	DX	DY	DZ
2	**Units (Height)**	**Additional Properties (if Applicable)**	**Original Data Row#**	**Status**	**Error Message**
3			1	Validation Error	Product Quantity Numeric Value (Column E): If "Units (Product Quantity)" is set, then "Product Quantity Numeric Value" 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.
4			2	Validation Error	Product Quantity Mass Numeric Value (Column H): If "Units (Product Quantity Mass)" is set, then "Product Quantity Mass Numeric Value" 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.
5			3	Validation Error	Portion Count Numeric Value (Column Q): If "Units (Portion Count)" is set, then "Portion Count Numeric Value" 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.
6			4	Validation Error	Length Numeric Value (Column V): If "Units (Length)" is set, then "Length Numeric Value" 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.
7			5	Validation Error	Width Numeric Value (Column X): If "Units (Width)" is set, then "Width Numeric Value" must have an entry. If you do not have values for a field, you must leave the cell bla Please refer to the Premarket Tobacco Product Applications and Record Keeping Requirements rule for the required properties based on product category and subcategory.
8			6	Validation Error	Diameter Format (Column AA): If "Units (Diameter)" is set, then "Diameter Format" 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. Diameter Numeric Value (Column AB): If "Units (Diameter)" is set, then "Diameter Numeric Value" 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.
					Portion Thickness Numeric Value (Column AD): If "Units (Portion Thickness)" is set, then "Portion Thickness Numeric Value" must have an entry. If you do not have values for

Figure 10: Issue Report Example® in Excel Format

16. Once the spreadsheet has been corrected, you can repeat steps 1-15 until the spreadsheet passes validation.

5 Application Log

The Application Log can be used to troubleshoot issues with the Product Validator Tool. The log is a reference for the Help Desk to identify and solve a problem with the tool. It is to be attached to an email to CTP eSub CTPeSub@fda.hhs.gov to assist in determining the problem experienced with the tool. This is the helpdesk email for the validator tool. Inquiries as well as application log should be sent here.

1. Select the **Application** button.

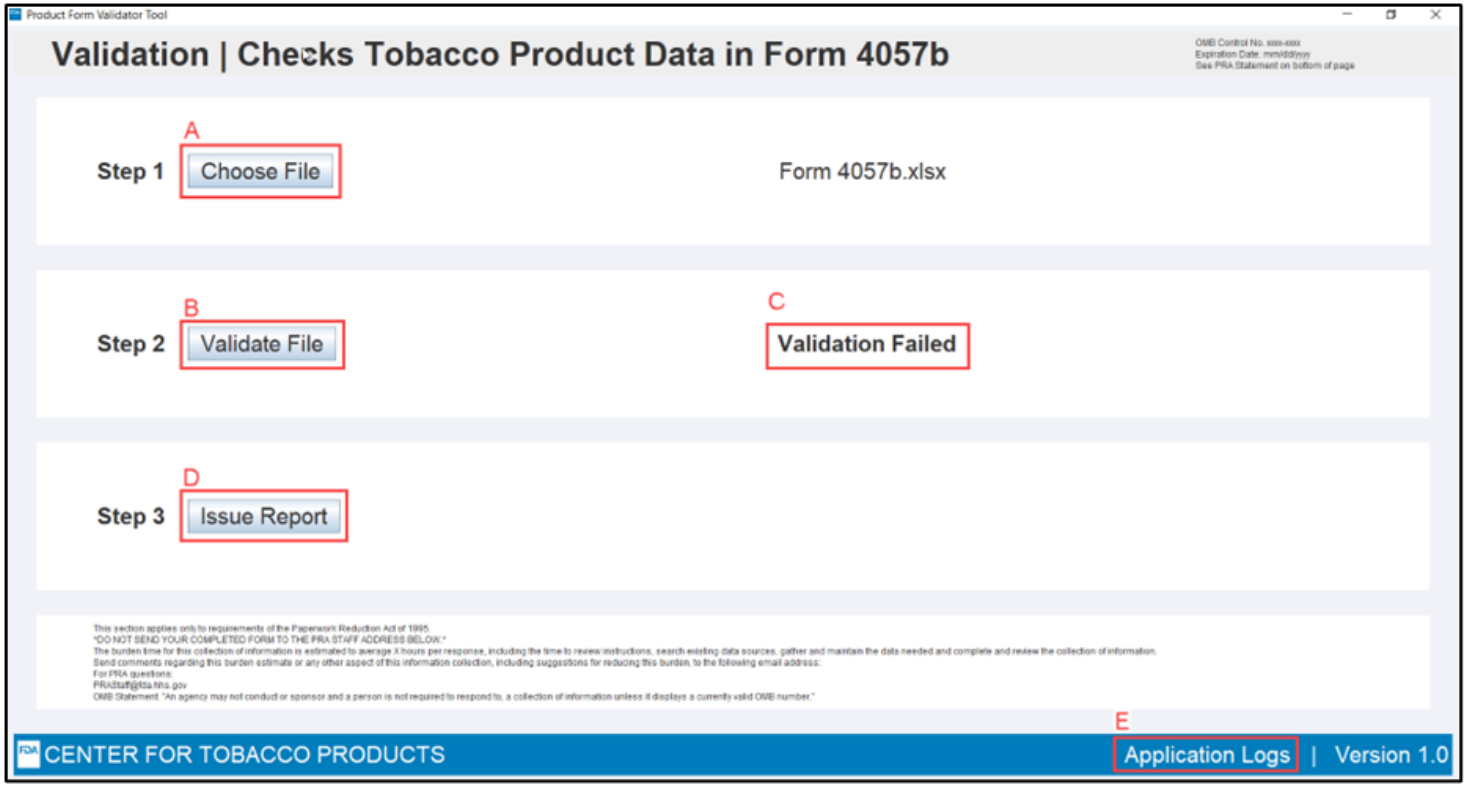


Figure 11: Application Log Button

Note: This will save the Application Log to a folder on your PC that you designate.

2. Browse and locate the desired folder on your PC where you would like the Application Log to be saved.
3. Click the **Save** button.
4. Navigate to the folder double-click the **Application Log** to open it.
5. Send an email with the attached Application Log to CTP eSub CTPeSub@fda.hhs.gov

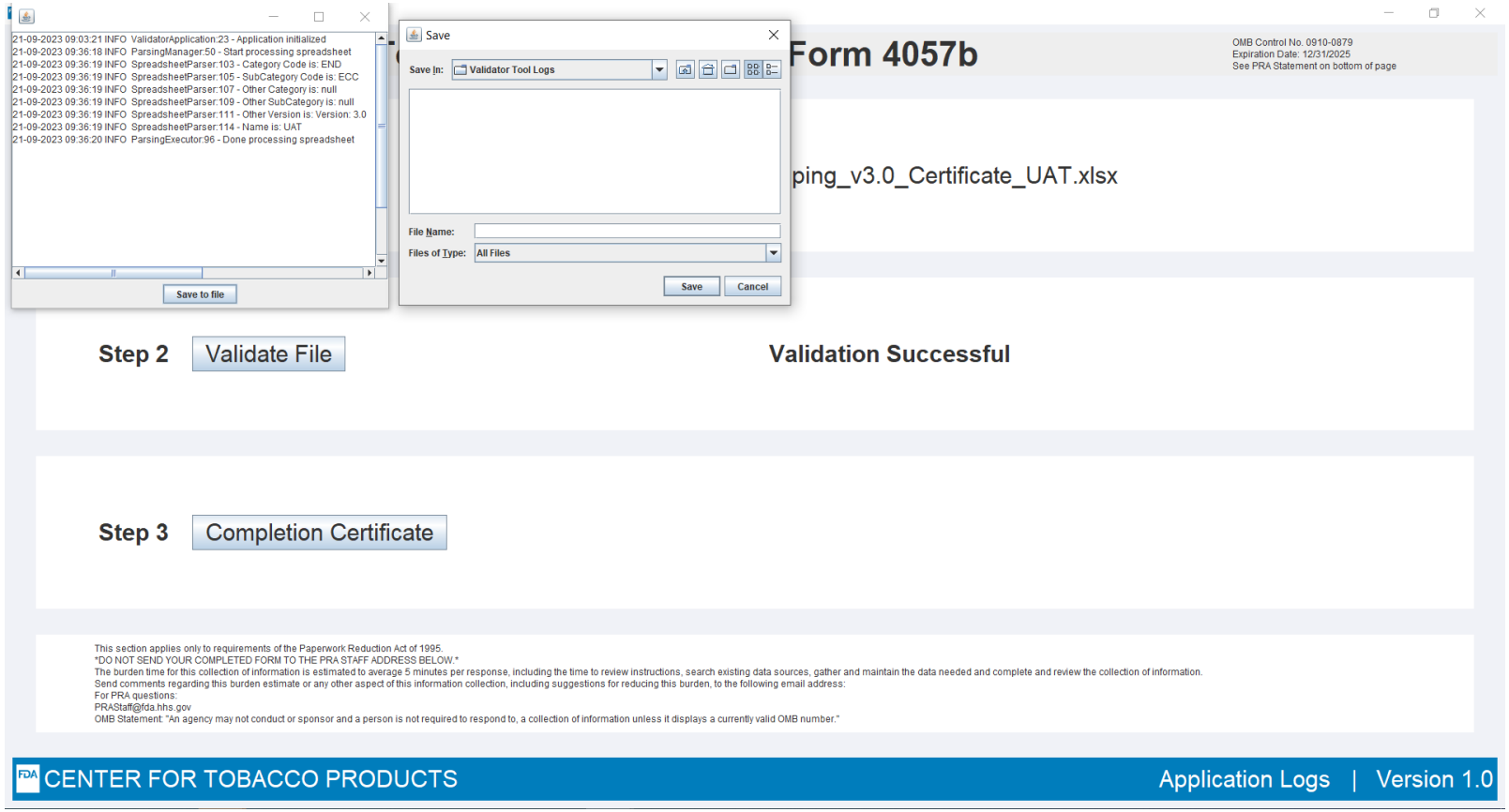


Figure 12: Application Log Results Example