

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

t of Figures	0
Introduction	1
1.1 System Requirements	1
1.2 Installing the Java Development Kit	1
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
Navigating the Tool	4
How to Use the Product Validator Tool	6
Application Log	.13
	Introduction

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



	S	ystem Pro	perties		×
Computer Name	Hardware	Advanced	System Protection	Remote	
	E	invironme	nt Variables		x
<u>U</u> ser vari	ables for He	lical			
Variable	2	Value			
TEMP		%USERPRO	FILE%\AppData\Lo	cal\Temp	
TMP		%USERPRO	FILE%\AppData\Lo	cal\Temp	
				7	
		<u>N</u> ew	<u>E</u> dit	<u>D</u> elete	
<u>S</u> ystem v	ariables				
Variable	2	Value		1	•
ComSpe	ec	C:\Windows	\system32\cmd.exe		
FP_NO	_HOST_C	NO			
NUMBE	R_OF_P	4	_		
OS		Windows_N	Γ	`	
		Ne <u>w</u>	Ed <u>i</u> t	Delete	

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\jdk1.8.0_101. Your version might have a different number.

Variable	Value				
OneDrive	C:\Users\Helical\OneDrive				
Path C:\Users\Helical\AppData\Local\atom\bin;C:\Users\Helical\AppDat FEMP %USERPROFILE%\AppData\Local\Temp FMP %USERPROFILE%\AppData\Local\Temp					
	New Edit Delete				
stem variables					
stem variables Variable	Value	,			
stem variables Variable ComSpec	Value C:\WINDOWS\system32\cmd.exe	,			
stem variables Variable ComSpec JAVA_HOME	Value C:\WINDOWS\system32\cmd.exe C:\Program Files\Java\jdk1.8.0_101	,			
stem variables Variable ComSpec JAVA_HOME MB_JETTY_PORT	Value C:\WINDOWS\system32\cmd.exe C:\Program Files\Java\jdk1.8.0_101 7080	,			
stem variables Variable ComSpec JAVA_HOME MB_JETTY_PORT NUMBER_OF_PROCESSORS OPENSSL_CONE	Value C:\WINDOWS\system32\cmd.exe C:\Program Files\Java\jdk1.8.0_101 7080 4 C:\Program Files\PostgreSQL\psglQDBC\etc\ppenssl.cpf	,			
stem variables Variable ComSpec JAVA_HOME MB_JETTY_PORT NUMBER_OF_PROCESSORS OPENSSL_CONF OS	Value C:\WINDOWS\system32\cmd.exe C:\Program Files\Java\jdk1.8.0_101 7080 4 C:\Program Files\PostgreSQL\psqIODBC\etc\openssl.cnf Windows NT				
stem variables Variable ComSpec JAVA_HOME MB_JETTY_PORT NUMBER_OF_PROCESSORS OPENSSL_CONF OS	Value C:\WINDOWS\system32\cmd.exe C:\Program Files\Java\jdk1.8.0_101 7080 4 C:\Program Files\PostgreSQL\psqlODBC\etc\openssl.cnf Windows_NT				

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)

U.S. Food and Drug Administration Protecting and Promoting Your Health

- 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:

Product Form Validator Tool	– 0 ×
Validation Checks Tobacco Product Data in Form 4057b	OMB Control No. xxxx-xxx Expiration Date: mm/dd/yyyy See PRA Statement on bottom of page
Step 1 Choose File Form 4057b.xlsx	
B C Step 2 Validate File Validation Failed	
Step 3 Issue Report	
This section applies only to requirements of the Papervion's Reduction Act of 1995. "DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW" The burden time for this collection of information is estimated to average X hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and comp Send comments regarding this burden estimate or any other aspect of this information collection, including the time to review instructions, search existing data sources, gather and maintain the data needed and comp Send comments the space regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following mail address: For PRAS questions: FOR VASSBB[gits And goV OMB Statement: "An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."	stete and review the collection of information.
CENTER FOR TOBACCO PRODUCTS	Application Logs Version 1.0

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.

Product F	orm Validator Tool	-	٥	\times
V	alidation Checks	Tobacco Product Data in Form 4057b		
	Step 1 Choose File	No File Selected		
	Step 2 Validate File	Validation Status		
	Step 3			

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.

Product Form Validate Tool		- 0 ×
Validation Checks Toba	cco Product Data in Form 4057b	OMB Control No. xxxx+xxxx Expiration Date: mm/ddlyyyy See PRA Statement on bottom of page
Step 1 Choose File	Form 4057b.xlsx	
	Dopen X	
Step 2 Validate File	Look (r: Testing v) (1) (1) (1) (1) (1) (1) (1) (1) (1) (
Step 3 Issue Report	File Name: ProductGrouping_v3.0_Certificate_UAT.stax Files of Type: All Files Cancel	

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.

Product Form Valid	ator Tool		-	٥	×
Valio	lation Checks Toba	cco Product Data in Form 4057b	OMB Control No. xxxx-xxxx Expiration Date: mm/ddlyyyy See PRA Statement on bottom of page		
St	ep 1 Choose File	ProductGrouping_v3.0_Certificate_UAT.xlsx			
St	ep 2 Validate File	Validation Status			
St	ер 3				

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.

Validation Ch	ecks Tobacco Product Data	a in Form 4057b	ONIO Control No, teor vani Experation Date: mmiddlyny See PRA Statement on beform of page	0 X
Step 1 Choose	File Produ	ctGrouping_v3.0_Certificate_UAT.xlsx		
Step 2 Validate	File	Validation Successful		
Step 3 Complet	ion Certificate			

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.

Product Form Validator Tool	- 0 ×
Validation Checks Tobacco Product Data in Form 4057b	OMB Control No.xxxxxxxx Expiration Date: mm/ddlyyyy See PRA Statement on bottom of page
Step 1 Choose File UAT_UnitsnoNumber.xlsx	
Step 2 Validate File Validation Failed	
Step 3 Issue Report	
This section applies only to requirements of the Paperwork Reduction Act of 1995. "DO NOT SEND YOUR COMPLETED FORM TO THE PRASTAFF ADDRESS BELOW." The complete and review the collection of the paper of the paper of the same of the paper	lection of information.
CENTER FOR TOBACCO PRODUCTS	Application Logs Version 1.0

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.

Au	toSave 💽 💽 🖓 - 🥲	ା ୍କ କୁ ଦ ⊽ UAT_UnitsnoNu	umber_Errors.xlsx • Las	t Modified: 2m ag	✓ Search (Alt+Q)			Greene, Ryan * 🔮	b –	ð
File	Home Insert Draw	v Page Layout Formulas	Data Review	View Help	Acrobat				Comments	🖻 Share
Past	Cut Calibri Copy ~ Sormat Painter	 ✓ 11 ✓ A[^] A[×] ✓ U × B[×] A[×] 	= = ₌ ≫ √ = = = = =	환 Wrap Tex 프 태 Merge &	ienter ~ \$ ~ % 9 5.00 300 Conc Formation	ditional Format as Cell atting ~ Table ~ Styles ~	Insert Delete Format	∑ AutoSum × AZY ↓ Fill × Sort & Find & Fild & Filter × Select ×	Sensitivity	
	Clipboard 🛛	Font 🕞	Ali	ignment	Number 🗔	Styles	Cells	Editing	Sensitivity	ļ
B12		fx								
	BA	BB	DX	DY			DZ			
2 Ui	nits (Height)	Additional Properties (if Applicable)	Original Data Row#	Status	rror Message					}
8			1	Validation Error Validation Error	Iroduct Quantity Numeric Value (Column E): If "L leld, you must leave the cell blank. Please refer to roduct category and subcategory. Iroduct Quantity Mass Numeric Value (Column H) ave values for a field, you must leave the cell bla roperties based on product category and subcate	Units (Product Quantity)" is set o the Premarket Tobacco Produ): If "Units (Product Quantity I ank. Please refer to the Premar agory.	, then "Product Quantity N ict Applications and Recor Mass)" is set, then "Produc ket Tobacco Product Appli	umeric Value" must have an entry. If d Keeping Requirements rule for the ru ct Quantity Mass Numeric Value" must cations and Record Keeping Requirem	you do not have va equired properties t have an entry. If ents rule for the re	you do not equired
5			3	Validation Error	Portion Count Numeric Value (Column Q): If "Uni nust leave the cell blank. Please refer to the Prem ategory and subcategory.	its (Portion Count)" is set, then narket Tobacco Product Applica	"Portion Count Numeric V ations and Record Keeping	alue" must have an entry. If you do no Requirements rule for the required pr	t have values for a operties based on	a field, you product
6			4	Validation Error	ength Numeric Value (Column V): If "Units (Leng Iank. Please refer to the Premarket Tobacco Prod ubcategory.	gth)" is set, then "Length Num duct Applications and Record K	eric Value" must have an e eeping Requirements rule	ntry. If you do not have values for a fi for the required properties based on p	eld, you must leav roduct category a	re the cell
7			5	Validation Error	Vidth Numeric Value (Column X): If "Units (Widti lease refer to the Premarket Tobacco Product Ap Viameter Format (Column AA): If "Units (Diameter lease refer to the Premarket Tobacco Product Ap Jameter Numer Value (Column AB): If "Units	th)" is set, then "Width Numeri plications and Record Keeping er)" is set, then "Diameter Form plications and Record Keeping Diameter)" is set, then "Diame	: Value" must have an ent Requirements rule for the nat" must have an entry. If Requirements rule for the Req Numeric Value" must f	ry. If you do not have values for a field required properties based on product you do not have values for a field, yo required properties based on product ave an entry. If you do not have value	l, you must leave t category and sub- u must leave the c category and subc s for a field, you m	the cell blans category. ell blank. category. nust leave
8			6	Validation Error	he cell blank. Please refer to the Premarket Tobac ubcategory.	cco Product Applications and R	ecord Keeping Requireme	nts rule for the required properties bas	sed on product cat	tegory and

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 <u>CTPeSub@fda.hhs.gov</u> 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 <u>CTPeSub@fda.hhs.gov</u>

≦ − □ ×			– 0 ×
21-09-2023 09 03 21 INFO ValidatorApplication 23 - Application initialized 21-09-2023 09 36:18 INFO ParsinglAnager.50 - Start processing spreadsheet 21-09-2023 09 36:19 INFO SpreadsheetParser.103 - Category Code is: ENC 21-09-2023 09 36:19 INFO SpreadsheetParser.105 - SubcCategory Code is: ECC 21-09-2023 09 36:19 INFO SpreadsheetParser.107 - Other Category Code is: ECC	Save X Save In: Validator Tool Logs Validator Tool Logs	0MB Control No. 0910-0879 Expiration Date: 1221/2025 See PRA Statement on botton	m of page
21-09-2023 09:36:19 INFO SpreadsheelParser:109 - Other SubCategory is: null 21-09-2023 09:36:19 INFO SpreadsheelParser:111 - Other Version is: Version: 3.0 21-09-2023 09:36:19 INFO SpreadsheelParser:114 - Name is: UAT 21-09-2023 09:36:20 INFO ParsingExecutor:96 - Done processing spreadsheel	ping_v3.0_	Certificate_UAT.xlsx	
<	File Name: Files of Type: All Files Save Cancel		
Step 2 Validate File	Validation St	uccessful	
Step 3 Completion Certifi	cate		
This section applies only to requirements of the Paperwork Reduction	Act of 1995.		
DO NOT SEND YOUR COMPLETED FORM TO THE PRASTAFF ADDRESS BELOW. The burden time for this collection of information is estimated to average 5 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following email address: For PRA questions: PRAStati@/da.hhs.gov OMB Statement: "An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."			
CENTER FOR TOBACCO PROD	UCTS	Application Logs	Version 1.0

Figure 12: Application Log Results Example