Validation Tool 2.0

Landing Page –

PMTA Success Path:

File Upload:

Validate File:

OK:

Click Completion Certificate:

Checks Tobacco Product Data Forms

Step 1   Choose File   Tobacco Company ABC.xlsx

Step 2   Validate File   ssful

Save

| Save In: | Documents |

- Custom Office Templates
- My Shapes
- OneNote Notebooks
- Visual Studio 2022
- workspace-spring-tool-suite-4-4.10.0.RELEASE

Folder name: C:\Users\Alexander.Meol\OneDrive - FDA\Documents

Files of Type: All Files

[Save]   [Cancel]

Step 3   Completion Certificate

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PMTA Certificate:

Certificate of FDA Form 4057b Validation

THIS ACKNOWLEDGES THAT

Test's

Successful Validation: Nov 5, 2024, 1:27:51 PM

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

File Name: Tobacco Company ABC.xlsx
Product Category: Cigars
Subcategory: Cigar Tobacco Filler
Total Products: 1

Validator Version: 2.0
Spreadsheet Version: 3.1

Nov 05, 2024

If you modify form 4057b after this validation Nov 5, 2024, 1:27:51 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

SE Success Path –

Same Screenshots as Above, Certificate is different.

Certificate of Form 3965b Validation

THIS ACKNOWLEDGES THAT

Test's

Successful Validation: Nov 5, 2024, 1:34:50 PM

Form 3965b Tobacco Substantial Equivalence Product Grouping Spreadsheet

File Name: Tobacco Company ABC.xlsx
Product Category: Cigars
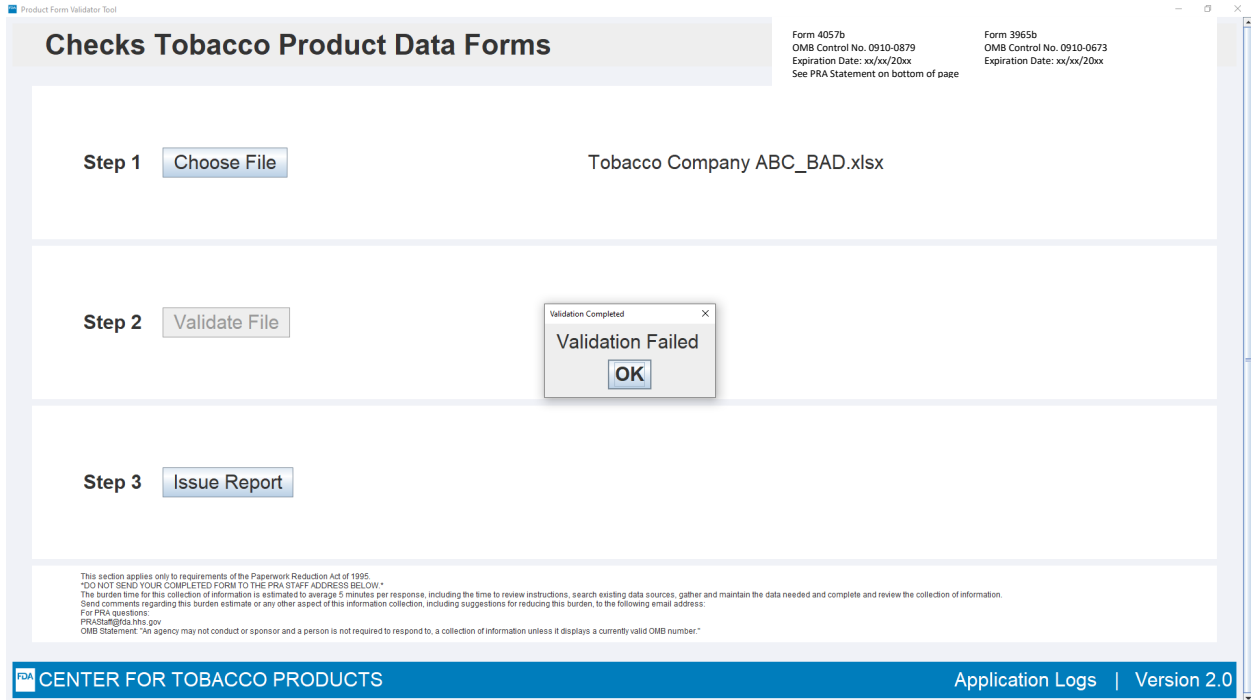Subcategory: Cigar Tobacco Filler
Total Products: 1

Validator Version: 2.0
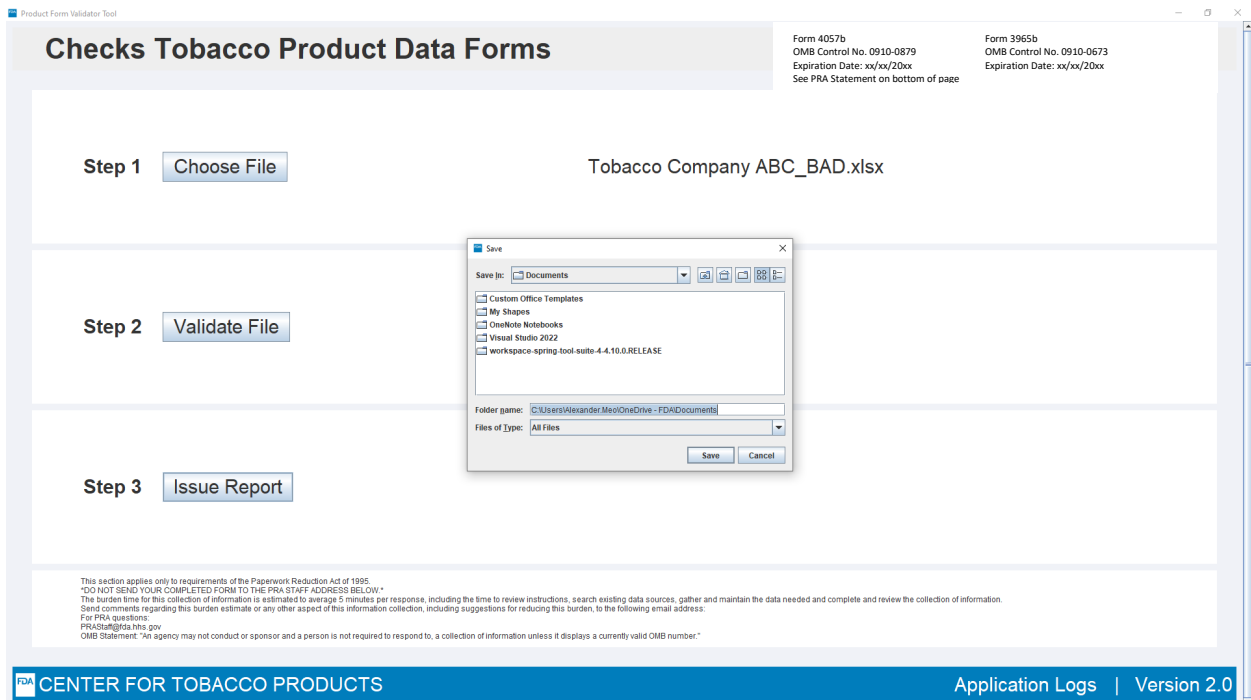Spreadsheet Version: 1.0

Nov 05, 2024

If you modify form 3965b after this validation Nov 5, 2024, 1:34:50 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
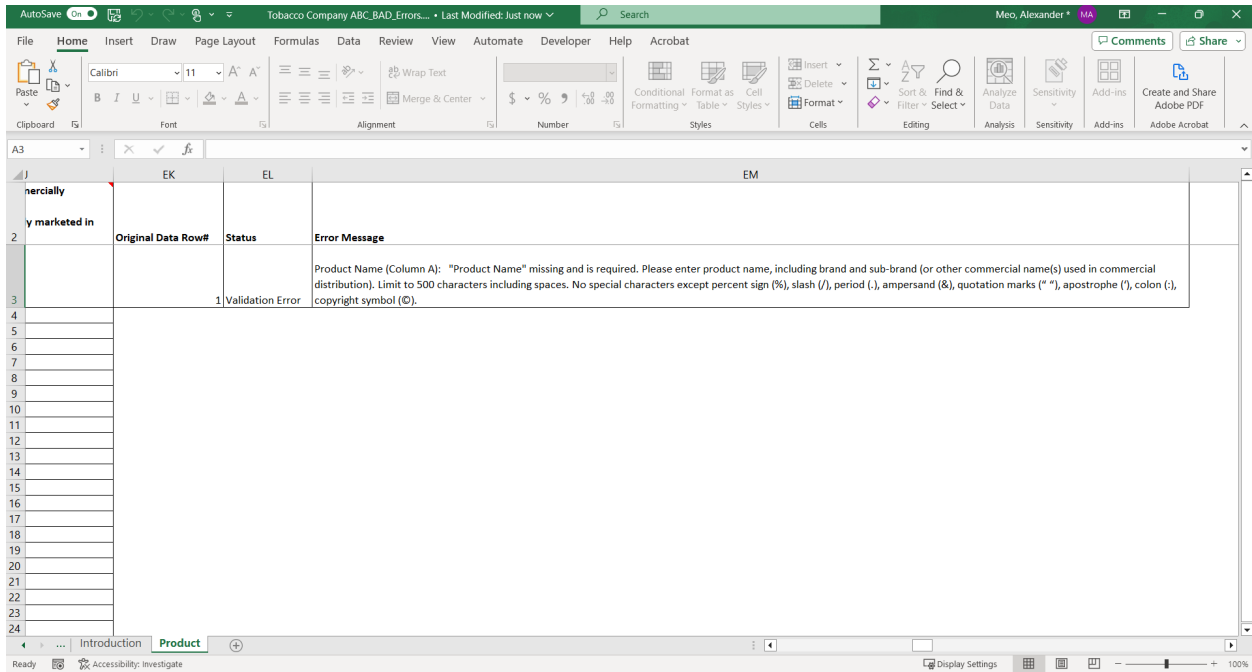
File Fails Validation:

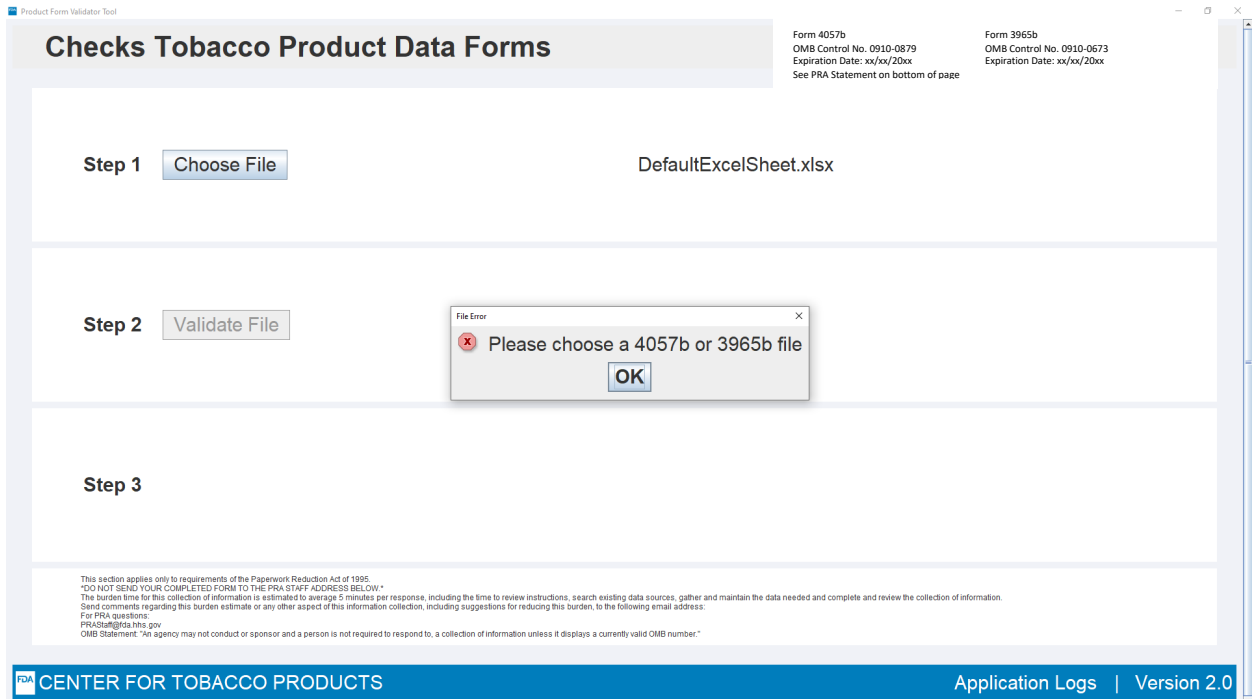**Checks Tobacco Product Data Forms**

Form 4057b
OMB Control No. 0910-0879
Expiration Date: xx/xx/20xx
See PRA Statement on bottom of page

Form 3965b
OMB Control No. 0910-0673
Expiration Date: xx/xx/20xx

Step 1   Choose File   Tobacco Company ABC_BAD.xlsx

Step 2   Validate File

Validation Completed   ×

Validation Failed

OK

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 PRA STAFF 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:
PRAStaff@fda.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."

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Issue Error Report:

Checks Tobacco Product Data Forms

Form 4057b
OMB Control No. 0910-0879
Expiration Date: xx/xx/20xx
See PRA Statement on bottom of page

Form 3965b
OMB Control No. 0910-0673
Expiration Date: xx/xx/20xx

Step 1   Choose File   Tobacco Company ABC_BAD.xlsx

Save   ×

Save In: Documents

Custom Office Templates
My Shapes
OneNote Notebooks
Visual Studio 2022
workspace-spring-tool-suite-4-4.10.0.RELEASE

Step 2   Validate File

Folder name: C:\Users\Alexander.Meoi\OneDrive - FDA\Documents
Files of Type: All Files

Save   Cancel

Step 3   Issue Report

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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."

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Error Report Example:

Error Messages:

Wrong Excel File-

Wrong PMTA Version –

Wrong SE Version –

File is in Use –

Checks Tobacco Product Data Forms

Step 1   Choose File   Tobacco Company ABC.xlsx

Step 2   Validate File

File Error   ✕

ⓧ Please close the Excel file, as the file is in use and cannot be read.

OK

Step 3

CENTER FOR TOBACCO PRODUCTS   Application Logs | Version 2.0