

1. Initial Screen

Validation | Checks Tobacco Product Data in Form 4057b

Step 1

Choose File

No File Selected

Step 2

Validate File

Validation Status

Step 3

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.*

2. Choose File

Validation | Checks Tobacco Product Data in Form 4057b

Step 1

Choose File

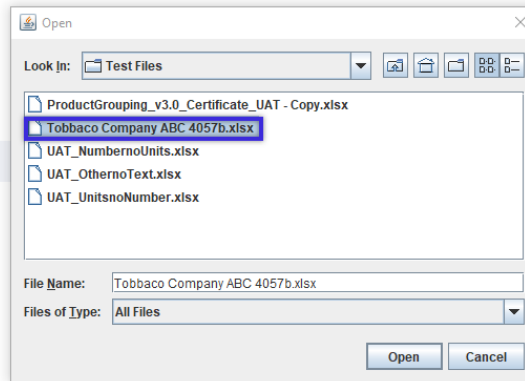
No File Selected

Step 2

Validate File

Validation Status

Step 3



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."

3. Validate File

Validation | Checks Tobacco Product Data in Form 4057b

OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

Step 1

Choose File

Tobacco Company ABC 4057b.xlsx

Step 2

Validate File

Validation Status

Step 3

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."

4. Validation Successful; Certificate Available

Validation | Checks Tobacco Product Data in Form 4057b

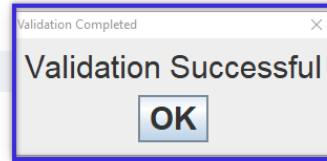
OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

Step 1

Tobacco Company ABC 4057b.xlsx

Step 2

Validation Successful



Step 3

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."

5. Save Certificate

Validation | Checks Tobacco Product Data in Form 4057b

OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

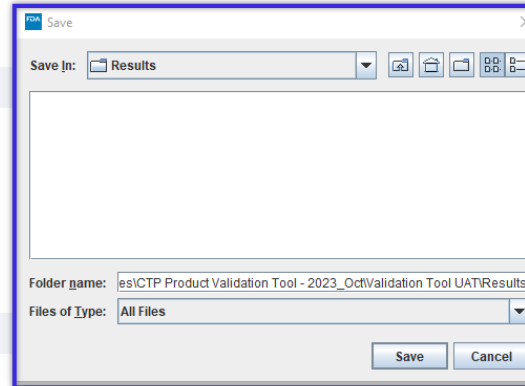
Step 1

Tobacco Company ABC 4057b.xlsx

Step 2

Validation Successful

Step 3



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."

6. Completion Certificate

Certificate of FDA Form 4057b Validation

THIS ACKNOWLEDGES THAT

Tobacco Company's

Successful Validation: Sep 7, 2023 8:40:41 AM

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

File Name: Tobacco Company ABC 4057b.xlsx
Product Category: Electronic Nicotine Delivery Systems (ENDS) (Vapes)
Subcategory: Closed E-Cigarette
Total Products: 1

Validator Version: 1.0
Spreadsheet Version: 3.0

September 07, 2023

If you modify form 4057b after this validation Sep 7, 2023 8:40:41 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

7. Select Bad File

Validation | Checks Tobacco Product Data in Form 4057b

Step 1

Choose File

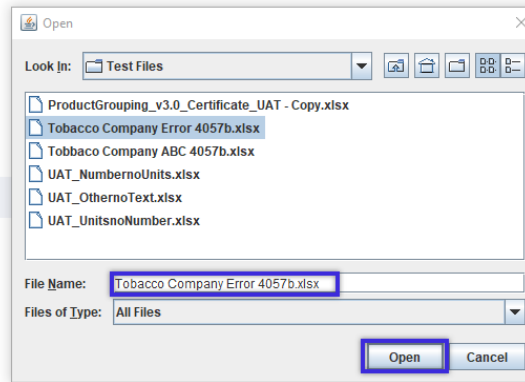
No File Selected

Step 2

Validate File

Validation Status

Step 3



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."

8. Validate Bad File

Validation | Checks Tobacco Product Data in Form 4057b

OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

Step 1

Choose File

Tobacco Company Error 4057b.xlsx

Step 2

Validate File

Validation Status

Step 3

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."

9. Validation Failed; Issue Report Available

Validation | Checks Tobacco Product Data in Form 4057b

Step 1

Tobacco Company Error 4057b.xlsx

Step 2

Validation Failed



Step 3

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."

10. Save Issue Report

Validation | Checks Tobacco Product Data in Form 4057b

OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

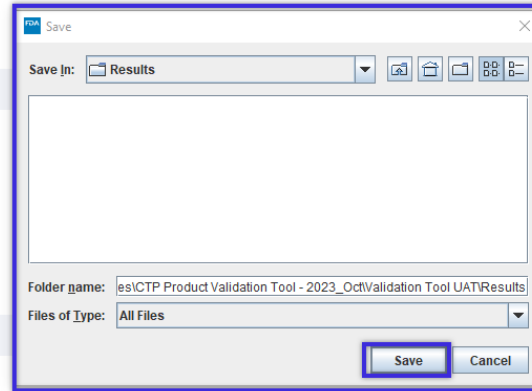
Step 1

Tobacco Company Error 4057b.xlsx

Step 2

Validation Failed

Step 3



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."

11. Sample Issue Report

Company B with Issues_Errors.xlsx • Last Modified: 2m ago

Search (Alt+Q)

File Home Insert Page Layout Data Review View Acrobat

Clipboard Font Alignment Number Styles Cells Editing

BB5 NA

BB	DX	DY	DZ
Additional Properties (if Applicable)	Original Data Row#	Status	Error Message
NA			<p>Characterizing Flavor (Column K): If "Characterizing Flavor", if Flavored has an entry, then "Characterizing Flavor" must equal 'Flavored'.</p> <p>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.</p> <p>Units (Portion Count) (Column R): Invalid entry for "Units (Portion Count)". "Units (Portion Count)" may not be allowed for this product category/subcategory. 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.</p>
	1	Validation Error	Nicotine Concentration Units (Column AJ): If product attribute "Nicotine Concentration Units", then units must equal mg/unit.
NA	2	Validation Error	<p>Characterizing Flavor (Column K): If "Characterizing Flavor", if Flavored has an entry, then "Characterizing Flavor" must equal 'Flavored'.</p> <p>Nicotine Concentration Units (Column AJ): If product attribute "Nicotine Concentration Units", then units must equal mg/unit.</p>
NA	3	Validation Error	<p>Characterizing Flavor (Column K): If "Characterizing Flavor", if Flavored has an entry, then "Characterizing Flavor" must equal 'Flavored'.</p> <p>Nicotine Concentration Units (Column AJ): If product attribute "Nicotine Concentration Units", then units must equal mg/unit.</p>

12. Error Message: File in Use

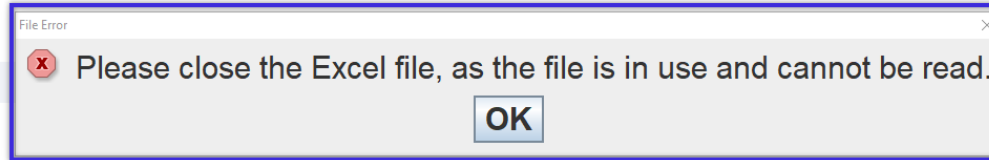
Validation | Checks Tobacco Product Data in Form 4057b

Step 1

ProductGrouping_v2.0_UAT.xlsx

Step 2

Validation Status



Step 3

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."

13. Error Message: Wrong 4057b Version

Validation | Checks Tobacco Product Data in Form 4057b


Step 1

ProductGrouping_v2.0_UAT.xlsx

Step 2

Validation Status

File Error ×

 The version of the 4057b spreadsheet needs to be 3.0.

Step 3

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."

14. Error Message: Not 4057b Excel File

Validation | Checks Tobacco Product Data in Form 4057b

OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

Step 1

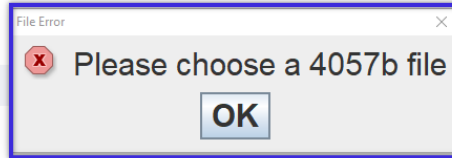
Choose File

Taxonomy.xlsx

Step 2

Validate File

Validation Status



Step 3

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."

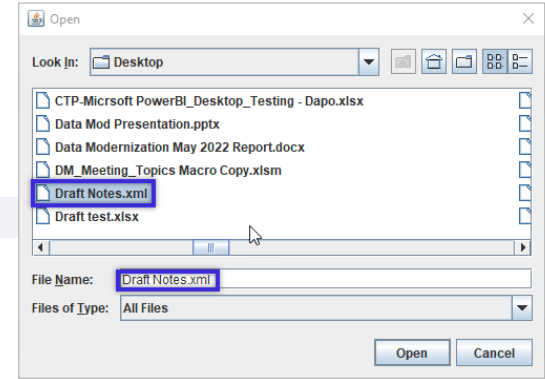
15. Error Message: Wrong File Type

Validation | Checks Tobacco Product Data in Form 4057b

OMB Control No. 0910-0879
Expiration Date: 12/31/2025
See PRA Statement on bottom of page

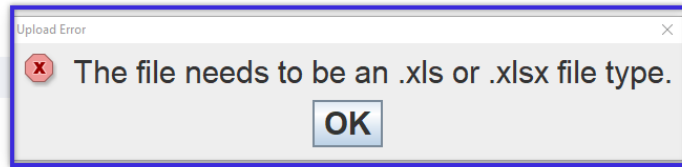
Step 1

No File Selected



Step 2

Validation Status



Step 3

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."

16. Sample Application Log

Validation | Checks Tobacco Product Data in Form 4057b

Step 1

Step 2

Step 3

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
Send comments regarding this burden estimate or any other aspect of this information collection, including suggestion
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 control number.

```

07-09-2023 08:17:31 INFO ValidatorApplication:23 - Application initialized
07-09-2023 08:32:26 INFO ParsingManager:50 - Start processing spreadsheet
07-09-2023 08:32:27 INFO SpreadsheetParser:103 - Category Code is: END
07-09-2023 08:32:27 INFO SpreadsheetParser:105 - SubCategory Code is: ECC
07-09-2023 08:32:27 INFO SpreadsheetParser:107 - Other Category is: null
07-09-2023 08:32:27 INFO SpreadsheetParser:109 - Other SubCategory is: null
07-09-2023 08:32:27 INFO SpreadsheetParser:111 - Other Version is: Version: 3.0
07-09-2023 08:32:27 INFO SpreadsheetParser:114 - Name is: Tobacco Company
07-09-2023 08:32:27 INFO ParsingExecutor:96 - Done processing spreadsheet
07-09-2023 08:38:04 INFO ParsingManager:50 - Start processing spreadsheet
07-09-2023 08:38:04 INFO SpreadsheetParser:103 - Category Code is: END
07-09-2023 08:38:04 INFO SpreadsheetParser:105 - SubCategory Code is: ECC
07-09-2023 08:38:04 INFO SpreadsheetParser:107 - Other Category is: null
07-09-2023 08:38:04 INFO SpreadsheetParser:109 - Other SubCategory is: null
07-09-2023 08:38:04 INFO SpreadsheetParser:111 - Other Version is: Version: 3.0
07-09-2023 08:38:04 INFO SpreadsheetParser:114 - Name is: Tobacco Company
07-09-2023 08:38:04 INFO ParsingExecutor:96 - Done processing spreadsheet
07-09-2023 08:45:44 INFO ParsingManager:50 - Start processing spreadsheet
07-09-2023 08:45:44 INFO SpreadsheetParser:103 - Category Code is: OTH
07-09-2023 08:45:44 INFO SpreadsheetParser:105 - SubCategory Code is: OTHR
07-09-2023 08:45:44 INFO SpreadsheetParser:107 - Other Category is: null
07-09-2023 08:45:44 INFO SpreadsheetParser:109 - Other SubCategory is: null
07-09-2023 08:45:44 INFO SpreadsheetParser:111 - Other Version is: Version: 3.0
07-09-2023 08:45:44 INFO SpreadsheetParser:114 - Name is: UAT
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #1
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #2
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #3
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #4
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #5
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #6
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #7
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #8
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #9
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #10
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #11
07-09-2023 08:45:45 INFO ProductRequestHandler:122 - xxx Spreadsheet row validation occurred on data row #12
07-09-2023 08:45:45 INFO ParsingExecutor:149 - Done processing issues spreadsheet
07-09-2023 08:45:45 INFO ParsingExecutor:96 - Done processing spreadsheet
07-09-2023 08:50:02 INFO ParsingManager:50 - Start processing spreadsheet
07-09-2023 08:51:36 INFO ParsingExecutor:96 - Done processing spreadsheet
07-09-2023 08:51:44 INFO ParsingManager:50 - Start processing spreadsheet
07-09-2023 08:51:45 INFO SpreadsheetParser:103 - Category Code is: END
07-09-2023 08:51:45 INFO SpreadsheetParser:105 - SubCategory Code is: ECC
07-09-2023 08:51:45 INFO SpreadsheetParser:107 - Other Category is: null
07-09-2023 08:51:45 INFO SpreadsheetParser:109 - Other SubCategory is: null
07-09-2023 08:51:45 INFO SpreadsheetParser:111 - Other Version is: Version: 2.0
07-09-2023 08:51:45 INFO SpreadsheetParser:114 - Name is: Tobacco Company
07-09-2023 08:51:45 ERROR ParsingExecutor:75 - general error: Previous import version not allowed. Please use new version
07-09-2023 08:52:33 INFO ParsingExecutor:96 - Done processing spreadsheet
07-09-2023 08:52:42 INFO ParsingManager:50 - Start processing spreadsheet
07-09-2023 08:52:42 ERROR ParsingExecutor:75 - general error: Introduction sheet not found from spreadsheet file [null]
07-09-2023 08:53:35 INFO ParsingExecutor:96 - Done processing spreadsheet

```