DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Premarket Tobacco Product Application Amendment and General Correspondence Submission

Form Approved: OMB Control No. 0910-0879
Expiration Date: 12/31/2024
(See Burden Statement on last page.)

The Applicant Identification section is comprised of three parts: Current Applicant Information; Request to Change Ownership; and the Addition, Update, Replacement, or Removal of information. Please provide the Applicant information most recently provided to the FDA under the heading: Subsection A: Current Applicant Information. Please provide the proposed new Applicant information under the heading: Subsection B: Request for Change in Ownership. The addition of other new information should be provided under the heading: Subsection C: Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact.

SECTION I – APPLICANT IDENTIFICATION

Subsection A.

Current Applicant Information *(The person or organization (manufacturer/importer) seeking a marketing granted order for a new tobacco product)*

Date of Submission

Name of Applicant *(Provide only either a person's name or an organization's name)*

Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title

Organization Name

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code

Current Contact Name *(Optional, for use only if Applicant is an organization)*

Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title
Telephone *(Include Country Code if applicable)*	FAX		Email Address

Organization Name and Address Information *(Optional, for use only if Applicant is an individual)*

Organization Name

Primary Address (Street Address, P.O. Box) ☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code

Subsection B.

Request for Change in Ownership

Proposed New Applicant Information *(Complete this section to change the current Applicant Information, the owner of the PMTA)*

Effective Date of Ownership Change

Name of Applicant *(Provide only either a person's name or an organization's name)*

Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title

Organization Name

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B Duns® Number

Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code
Telephone *(Include Country Code if applicable)*	FAX	Email Address

New Contact Name *(Optional, for use only if Applicant is an organization)*

Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title
Telephone *(Include Country Code if applicable)*	FAX		Email Address

Organization Name and Address Information *(Optional, for use only if Applicant is an individual)*

Organization Name

Primary Address (Street Address, P.O. Box) ☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code

☐ A notice is included stating that all of the former applicant's rights and responsibilities relating to the PMTA have been transferred to the new applicant.

☐ A notice is included stating the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the PMTA.

Transfer Requests

☐ Request to transfer all related submissions for the named product(s) to the new owner

Tobacco Product Name (Brand/Sub-brand)

Related Submissions: List the FDA Submission Tracking Numbers (STNs) for all your previous submissions for the tobacco product.

Related Submission Type	Related Submission STN	Submission Date

Subsection C.

Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact (Optional)

Addition, Update, Replacement, or Removal of Applicant Identification Information

If "Add" or "Replace" (not allowed for Current Applicant Information; use Subsection B.) is selected, provide all demographic information for the new party.
If "Update" is selected, provide only Person's Name and/or Organization's Name and the information which will replace previously submitted information.
If "Remove" is selected, provide only the Person's Name and/or Organization's Name of the party to be removed.

Select type of Applicant Identification Information (Select only one)

☐ Applicant (Address and Contact information only) ☐ Authorized Representative ☐ U.S. Agent

☐ Manufacturer

Effective Date of Change

Select one *(If "Update" is selected, FDA will update the Applicant Identification address or contact information that was previously submitted):*

☐ Add ☐ Update ☐ Replace ☐ Remove

Person's Name *(Provide a person's name for Authorized Representative or U.S. Agent; optional for the Manufacturer)*

Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title

Organization Name (Provide an organization name for the Manufacturer)

Address and Contact Information

Primary Address (Street Address, P.O. Box; Provide the postal address for the Authorized Representative; optional for the Manufacturer or the U.S. Agent)

Street Address (Provide the physical location for the Manufacturer or the U.S. Agent; optional for the Authorized Representative

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code
Telephone *(Include Country Code if applicable)*	FAX	Email Address

New Contact Name *(Optional, for use only if Applicant is an organization; do not use in conjunction with Subsection B)*

Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title
Telephone *(Include Country Code if applicable)*	FAX		Email Address

Organization Name and Address Information *(Optional, use for the Applicant only if a person (do not use in conjunction with Subsection B); also may be used for Authorized Representative, or U.S. Agent)*

Organization Name

Primary Address (Street Address, P.O. Box) ☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code

Addition, Update, or Removal of Point of Contact

If "Add" is selected, provide all demographic information for the new party.
If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.
If "Remove" is selected, provide only the Company/Institution Name of the party to be removed.

Select type of Point of Contact Information (Select only one)

☐ Applicant ☐ Manufacturer *(Other than Applicant)* ☐ Authorized Representative

☐ U.S. Agent ☐ Other, Regulatory ☐ Other, Technical

Select one *(If "Update" is selected, FDA will update the Point of Contact address or contact information that was previously submitted):*

☐ Add ☐ Update ☐ Remove

Alternate Point of Contact Name

Company Name			
Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title

Alternate Point of Contact Address and Contact Information

Primary Address (Street Address, P.O. Box)		
Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code
Telephone *(Include Country Code if applicable)*	FAX	Email Address

SECTION II – TOBACCO PRODUCT INFORMATION

(Note: Use this section to correct previously submitted information. This section is not intended to be used in place of submissions required for modifications for new tobacco products)

Unique Identification of Previously Submitted New Tobacco Product

(This Subsection is optional and to be used only to change previously submitted information
For individual tobacco products, fill in the Individual Tobacco Product sub-section below.
For a co-packaged tobacco product, complete Section II for each new tobacco product included within the co-package.
For grouped submissions complete a separate Section II for each tobacco product.)

Individual Tobacco Product
(Only the Previously Submitted New Tobacco Product Name is required. Provide other information only for updates to previously submitted information. Refer to Form 4057, Section VIII, Appendix B to select the appropriate Product Category and Subcategory or Tobacco Product Properties.)

Select to Update or Withdraw New Tobacco Product ☐ Update ☐ Withdraw

Previously Submitted New Tobacco Product Name (Brand/Sub-Brand)

Updated New Tobacco Product Name (Brand/Sub-Brand) *(if applicable)*

Update New Tobacco Product Category or Subcategory or Update New Tobacco Product Subcategory
(Complete only if Category or Subcategory is different than previously submitted)

Previously Submitted New Tobacco Product:

Category: Subcategory:

Updated New Tobacco Product:

Category: Subcategory:

Tobacco Product Properties Needed to Uniquely Identify the Product
(Update previously submitted Tobacco Product Properties Needed to Uniquely Identify Product by selecting Add, Update, or Remove and providing the Property Name. When updating properties provide both the previously submitted target value and the updated target value for the previously submitted new tobacco product.)

		New Tobacco Product Name (*as provided above)*	
Action *(Add, Update, Remove)*	Property Name	Previously Submitted Target Value	Updated Target Value

To submit information on additional tobacco product(s), use one or more copies of Section II as appropriate.

SECTION III – SUBMISSION INFORMATION

Type of Submission (Select only one)

☐ Amendment (If selected, provide Date of FDA Letter, if applicable; select Amendment Response Type; and indicate the Scientific Content in Section IV - Amendment Contents)

☐ General Correspondence *(if selected, provide Subject of Correspondence)*

FDA Submission Tracking Number *(STN)* to be amended:

Date of FDA Letter *(if applicable mm/dd/yy):*

Amendment Response Type (Select one)

☐ Deficiency Letter

☐ Unsolicited (Describe in Submission Summary)

☐ Other (Describe in Submission Summary)

Subject of Correspondence (Select all that apply)

- ☐ Request for Change in Ownership (Section I)
- ☐ Change in Authorized Representative, U.S. Agent, or Manufacturer Address or Contact Information (Section I)
- ☐ Addition or Removal of a Point of Contact (Section I)
- ☐ Update to Unique Identification Information (Section II)
- ☐ Change in Cross-referenced Content or Related Submissions (Section III)
- ☐ Change in Submission Contents (Section IV)
- ☐ Change in Manufacturing/Packaging/Sterilization Site Information (Section V)
- ☐ Adverse Experience Report (Describe in Submission Summary)
- ☐ Periodic Report (e.g., Annual Report) (Describe in Submissioin Summary)
- ☐ Request to Withdraw the PMTA
  - ☐ Select to indicate if the withdrawal is due to a health or safety concern related to the tobacco product
- ☐ Other (Describe in Submission Summary)

Submission Summary *(Required if instructed to "Describe" by a previous selection)*

Purpose of Application (Check only one)

- ☐ This PMTA Amendment is for a single new tobacco product
- ☐ This PMTA Amendment is for a group of PMTA Amendments containing multiple new tobacco products with similar modifications in comparison to one predicate tobacco product

Cross-referenced Content
(Optional, use this subsection to add new cross-referenced content, or update or remove previously submitted information)

Select to Add, Update, or Remove Cross-referenced Content

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Cross-referenced Content is relevant to all amended products in this submission

Identify Cross-referenced Submission Types as one of the following: PMTA, Tobacco Product Master File, or Modified Risk Tobacco Product (MRTPA)

Cross-referenced Submission Type	Cross-referenced Submission STN

Related Submissions
(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN

Formal Meetings Held with FDA pertaining to this tobacco product
(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.
(Refer to Form 4075, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative
(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans
(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Inspections
(List the categories of Inspections content provided by this Amendment)

Scientific Content
(Select the categories of Scientific Content provided by this Amendment)

Description of Scientific Content:

Check all that apply

- ☐ General Information
- ☐ Descriptive Information
- ☐ Product Samples
- ☐ Statement of Compliance with 21 CFR part 25
- ☐ Summary
- ☐ Product Formulation
- ☐ Manufacturing
- ☐ Other (Specify below)
- ☐ Literature Search
- ☐ Organized References
- ☐ Health Risk Investigations
- ☐ Study Report(s)
- ☐ Case Report Form(s)
- ☐ Analyzable Data Set(s)

Other Content *(Describe the other content provided by this Amendment)*

SECTION V – MANUFACTURING/PACKAGING/STERILIZATION SITE RELATING TO A SUBMISSION

(This section is optional.
If "Add" is selected, provide all demographic information for the new site.
If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.
If "Remove" is selected, provide only the Company/Institution Name of the site to be removed.)

Select to Add, Update, or Remove Manufacturing/Packaging/Sterilization Site

☐ Add ☐ Update ☐ Remove

Company/Institution Name

Specify type of Manufacturing/Packaging/Sterilization site

☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Re-packer/Relabeler

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Division Name (if applicable)

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code
Telephone *(Include Country Code if applicable)*	FAX	Email Address

Contact Name			
Prefix *(e.g., Mr., Mrs., Dr.)*	First Name	M.I.	Last Name
Generational Suffix *(e.g., Jr., III)*	Professional Suffix *(e.g., MD, Ph.D.)*		Position Title

The Manufacturing/Packaging/Sterilization Site is ready for inspection ☐ Yes ☐ No

SECTION VI – CERTIFICATION STATEMENT

Select one of the following, then enter Name of Appliant (or person signing on behalf of the Applicant if Applicant is an organization), Authorized Representative, or U.S. Agent, and the name of the Applicant in the body of the statement.

I am signing as a/an: ☐ Applicant ☐ Authorized Representative ☐ U.S. Agent

I,	First Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

on behalf of the applicant,

hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that records remain readily available to the FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

Signature	Date

APPENDIX
INSTRUCTIONS FOR USE

This form and the instructions for use are solely intended to provide the applicant an organized format to supply information required for a Premarket Tobacco Product Application (PMTA) Amendment and General Correspondence Submission.

Section I – Applicant Identification

Subsection A – Current Applicant Information

- Complete the Date of Submission
- Complete Name of Applicant name and optionally other identifying information. Provide only either a person's name, if the Applicant is an individual, or an Organization Name.
- Complete Applicant address information as previously submitted, and optionally provide contact name,telephone, and email address. (Changes to the current Applicant information should be made only in Subsection C.)
- If the Applicant is an individual, the Organization Name and Address associated with the individual may be provided.

Subsection B – Request for Change in Ownership 21 CFR 1114.13

- Provide the effective date of the change in ownership.
- Complete the Name of the New Applicant and optionally other identifying information. Provide only either a person's name, if the Applicant is an individual, or an Organization Name.
- Provide the Applicant address information, and optionally provide contact name, telephone, and email address.
- If the Applicant is an individual, the Organization Name and Address associated with the individual may be provided.
- Indicate if any notices are included in the submission regarding the transfer of ownership. (List the notice(s) in Section IV under Administrative contents.)
- Indicate if you are transferring all related submissions related to a brand or brands. If so, provide the tobacco product names and corresponding STNs subject to the change in ownership

Subsection C – Addition, Update, or Removal of Applicant Identification Information or Point of Contact 21 CFR 1114.9

- Optionally select the type of Applicant information (e.g., Applicant, Authorized Representative, etc.) being provided.
- Optionally select to add, update, replace, or remove Applicant Information.
- To add a new party, complete all information. An Authorized Representative or U.S. Agent must be a person. Provide the person's name, address, and contact information.
- To update or remove party information, the Person's Name or Organization Name must match previously submitted information. For updates, the Address and Contact information provided will be used to update previously provided information.
- To replace a party, the Person's Name or Organization Name must match previously submitted information. It is not necessary to provide address information.
- To provide additional Applicant Identification Information, select "Update Additional Applicant Identification Information" on the form.
- Optionally select the type of Point of Contact information (e.g., Applicant, Authorized Representative, etc.) being provided.
- Optionally select to add, update, or remove Point of Contact information.
- Provide the Company Name associated with the Point of Contact
- To add a new Point of Contact, complete all information. Provide the contact's name, address, and contact information.
- To update or remove information for a Point of Contact, the Person's Name must match previously submitted information.
- To provide information for an addition Point of Contact, the Person's Name must match previously submitted information

Section II – Tobacco Product Identification 21 CFR 1114.7(c)

- For an individual tobacco product, provide the previously submitted new tobacco product's names.
    - Product category, sub-category, and product properties should be provided only if they are changing. When updating product category, sub-category, or properties always give the both previously submitted and the updated information.
- For a co-packaged tobacco product, provide the new tobacco products' names for all products in the co-packaged tobacco product.
    - Product category, sub-category, and product properties should be provided only if they are changing. When updating product category, sub-category, or properties always give the both previously submitted and the updated information.
- For a grouped submission, add an individual or co-packaged tobacco product by selecting "Add Section II" on the form.

Section III – Submission Information

- Indicate whether the submission is an Amendment or General Correspondence.
    - For Amendments, provide the Date of FDA Letter, if applicable, and select the Amendment Response Type. If the type of response, is "Unsolicited" or "Other", describe the purpose of the submission in the Submission Summary. Also indicate the subject of the amendment provided in Section IV – Amendment and General Correspondence Contents.
    - For General Correspondence, select Subject(s) of Correspondence and provide the appropriate information in the Section indicated. If "Other", describe the subject of the correspondence in the Submission Summary. Also describe the subject of the correspondence in Section IV - Amendment and General Correspondence Contents
- Provide the FDA STN being amended. The Premarket Tobacco Application Amendment and General Correspondence Submission should be used to update only one STN.
- If instructed to do so, based on the selection of either Amendment Response Type or Subject of Correspondence, or otherwise optionally, complete the Submission Summary.
- Indicate whether the Amendment submission is for a single individual tobacco product or for a group of tobacco products previously submitted as a grouped PMTA submission.
- Optionally add, update, or remove cross-referenced content, including Tobacco Product Master Files
    - Provide the New Tobacco Product Name for which the cross-referenced content is relevant. Optionally, indicate if the content is relevant to all tobacco products which are the subject of this amendment submission. By selecting this checkbox, multiple products can be updated with one Section III. However, a Section II must be completed for each product updated by this amendment submission.
    - Provide metadata for each document to identify the cross-referenced content.
    - Select "Update Cross-Referenced Content Information" to add metadata for an additional document.
- Optionally add, update, or remove related submissions, (e.g., ITP, SE Report, MRTPA).
    - Provide the New Tobacco Name for which the related submission is relevant. Optionally, indicate if the submission is relevant to all tobacco products which are the subject of this amendment submission. By selecting this checkbox, multiple products can be updated with one Section III. However, a Section II must be completed for each product updated by this amendment submission.

Section IV – Amendment and General Correspondence Contents

- Select the categories of document submitted from among Administrative, Labeling and Marketing Plans, Inspections, Scientific Content, or Other. For each category (except Scientific Content), list the sub-categories that describe the submission contents. For Scientific Content, select the all the content categories that apply to content provided in this amendment submission. For Scientific Content that does not fit into one of the listed categories, select “Other” and describe the content in the space provided.
- Submission Table of Contents: Optionally, select to add, replace, or suspend (i.e., remove from the active documents for review) submission documents. Provide metadata for each submission document: Action (Add, Replace, or Suspend), Date Document was Submitted if replacing or suspending, Document Filename, Document or Study Title, Table of Contents Category, and all applicable Document Keywords.
- To provide metadata for additional documents select “Update Submission Document”. (A Sample of Table of Contents can be found in CTP’s “Electronic Submission File Formats and Specifications”, Appendix A. The technical specification is posted on CTP’s public website page at the very bottom of the “Manufacturing” page under “Resources for Electronic Submissions”: https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing)

Section V – Manufacturing/Packaging Sites Relating to a Submission

- Optionally select to add, update, or remove Manufacturing/Packaging Site information. To update or remove information for a Manufacturing/Packaging Site, the “Company/Institution Name” must match previously submitted information.
- If "Add" is selected, provide all demographic information for the new site. If "Update" is selected, provide only “Company/ Institution Name” and the information which will replace previously submitted information. If "Remove" is selected, provide only the "Company/ Institution Name" of the site to be removed.

Section VI – Certification Statement 21 CFR 1114.7(m)

- Select if the signer is acting as an Authorized Representative or U.S. Agent.
- Insert the name of the signer, and sign and date the form where indicated.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 10 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:

Department of Health and Human Services Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."