Login

CTP Portal NextGen uses the FDA's Single Sign On (SSO) account for authentication of users.

Log In Using FDA SSO

What is the CTP Portal?

The U.S. Food and Drug Administration's (FDA), Center for Tobacco Products (CTP) developed the CTP Portal as part of its initiative to improve submission processing and to foster interaction with Industry. The CTP Portal allows Industry to use the embedded upload feature to transmit eSubmitter-generated submissions; this new transmission method offers Industry an alternative to the Agency's existing WebTrader Hosted Solution. The eSubmission File Formats and Specifications document is available to provide an overview of the technical file formats and data specifications related to submitting electronic files to CTP.

The CTP Portal is intended for use by regulated tobacco Industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

The CTP Portal does not replace existing FDA systems and corresponding requirements, including but not limited to Tobacco Registration and Product Listing submissions made via the FDA Unified Registration Listing Systems (FURLS).

How to Get Access

Each regulated tobacco organization should have one or more Industry Account Managers (IAMs) who assume responsibility for managing users of the CTP Portal for their respective organization. These Industry Account Managers are able to add new users, grant corresponding user roles and permissions, lock and unlock user accounts, and edit information for existing user accounts.

If your organization has an IAM: If other members in your organization currently have user accounts, we encourage you to reach out to your organization's Industry Account Manager and request that they create a new user account on your behalf. They will be able to designate the appropriate user role for your account, including designating you as an Industry Account Manager, if appropriate.

If your organization does not have an IAM: If you are not aware of any members of your organization currently having CTP Portal user accounts, please request an Industry Account Manager (IAM) account. CTP staff will review your request and communicate CTP Portal User account updates as they become available.

Supported Browsers

For optimal performance, we recommend using Internet Explorer (IE) 11, or the latest versions of Mozilla Firefox or Google Chrome.

If using Internet Explorer (IE) 10, or earlier versions of Firefox and Chrome, you may experience minor visual deviations and limitations. Please note older browsers such as Safari 5 and below, IE 9 and below, as well as Linux/Unix specific browsers (e.g., Konqueror, Camino) are not supported.

Computer Security

Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of information being entered.

Security Warning

- This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.
- This system is provided for Government-authorized use only.
- Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.
- Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.
- By using this system, you understand and consent to the following:
    - The Government may monitor, record, and audit your system usage of personal devices and email system for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this system.
    - Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

Accept Reject

FDA CTP PORTAL NEXT GENERATION

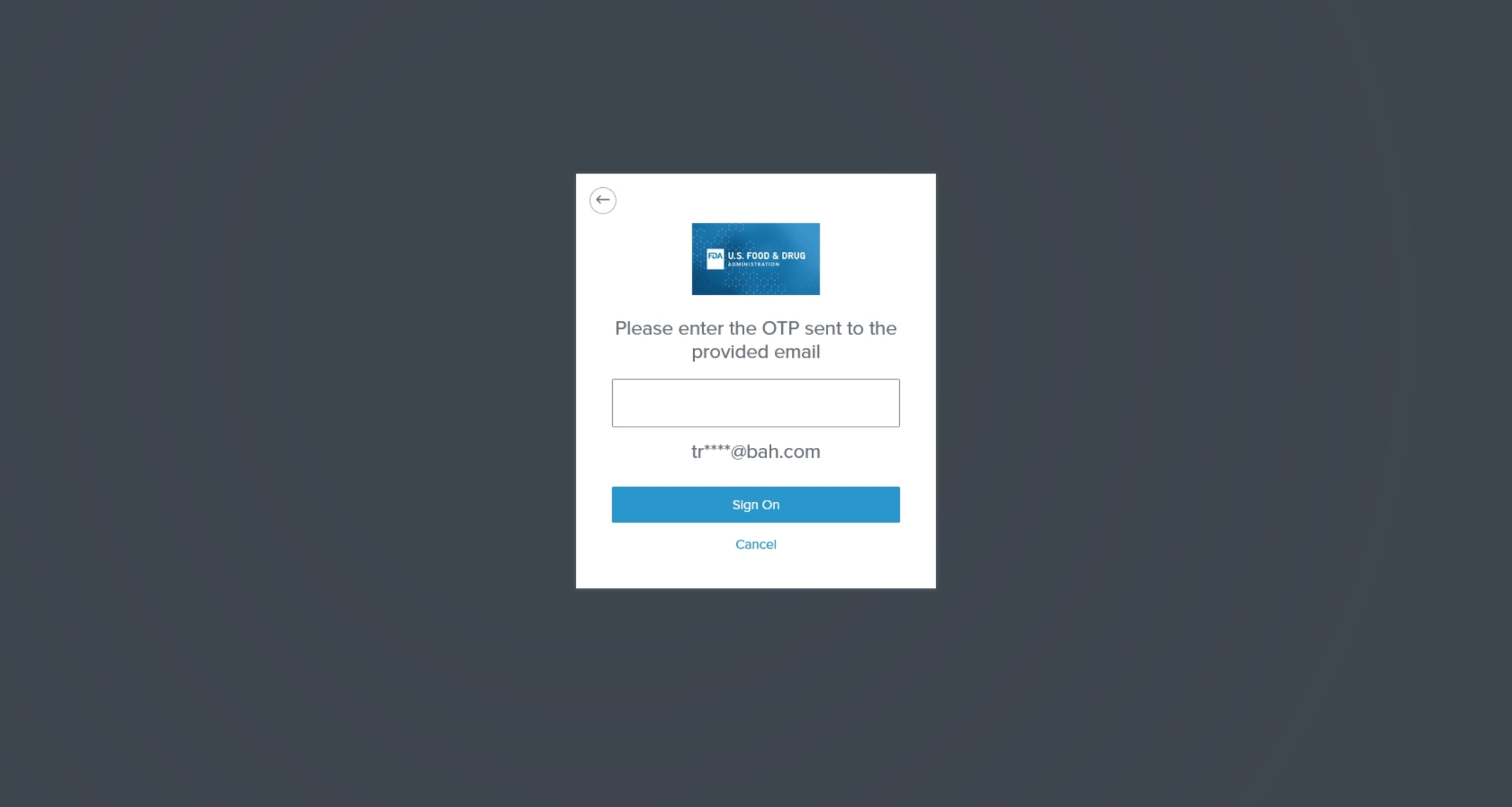
EMAIL

PASSWORD

Sign On

Change Password | Forgot Password

Don't have an account? Register now


U.S. FOOD & DRUG
ADMINISTRATION
Please enter the OTP sent to the provided email
tr****@bah.com
Sign On
Cancel

Welcome to CTP Portal NextGen

The U.S. Food and Drug Administration's (FDA), Center for Tobacco Products (CTP) developed the CTP Portal NextGen as part of its initiative to improve submission processing and facilitate interaction with industry stakeholders. The CTP Portal NextGen allows industry stakeholders to create, prepare, and deliver submissions all in one place; this new transmission method offers industry stakeholders an alternative to the Agency's existing WebTrader Hosted Solution. The eSubmission File Formats and Specifications document is available to provide an overview of the technical file formats and data specifications related to submitting electronic files to CTP.

The CTP Portal NextGen is intended for use by stakeholders in the regulated tobacco industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal NextGen should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

The CTP Portal NextGen does not replace existing FDA systems and corresponding requirements, including but not limited to Tobacco Registration and Product Listing submissions made via the FDA Unified Registration Listing Systems (FURLS).

Recent Regulatory Files

Date Issued	File Type	STN
10/03/2023	Substantially Equivalent Letter	SE0044966
08/14/2023	Substantially Equivalent Letter	SE0043394
06/30/2023	Acknowledgment Letter	PM0024019
04/22/2022	Refuse to Accept Letter	PM0022778
03/12/2022	Meeting Request Granted Letter	TC0000083

Displaying 5 most recent View All

Recent Notifications

Date	Message
12/01/2023 04:38 PM	A new submission has been submitted to CTP
08/31/2023 01:03 PM	A submission is now available for viewing
06/02/2023 10:38 AM	A new user has been added to your Organization
06/01/2023 10:43 AM	A submission is now available for viewing
05/20/2023 07:16 PM	The CTP Portal User Admin has been changed

Displaying 5 most recent View All

Recent Published Submissions

STN	Package ID	Submission Type	Version Type	Date Submitted
PM0001402	PKG0000900	PMTA - PreMarket Tobacco Application	Original	02/28/2025
PM0001401	PKG0000900	PMTA - PreMarket Tobacco Application	Original	02/28/2025
PM0001400	PKG0000850	PMTA - PreMarket Tobacco Application	Amendment	02/21/2025
PM0001399	PKG0000800	PMTA - PreMarket Tobacco Application	Original	02/14/2025
TC0001300	PKG0000750	TC - Meeting Request	Original	02/10/2025

Displaying 5 most recent View All

Recent Sent Submission Packages

Package ID	Package Name	Submission Type	Version Type	Date Submitted
PKG0000900	Test Company A PMTA - Products 200-299	PMTA - PreMarket Tobacco Application	Original	02/28/2025
PKG0000850	Test Company A PMTA Amendment - PM0001400	PMTA - PreMarket Tobacco Application	Amendment	02/21/2025
PKG0000800	Test Company A PMTA - Multiple Products	PMTA - PreMarket Tobacco Application	Original	02/14/2025
PKG0000750	Test Company A Meeting Request for Multiple Products	TC - General Correspondence	Original	02/10/2025
PKG0000700	Test Company A SE - Multiple Products	SE - Substantial Equivalence Application	Original	02/08/2025

Displaying 5 most recent View All

Recent Draft Submission Packages

Package ID	Package Name	Submission Type	Version Type	Date Created
PKG0000905	Test Company A PMTA - Product 300	PMTA - Premarket Tobacco Application	Original	03/10/2025
PKG0000895	Test Company A PMTA Amendment - PM0001400	PMTA - Premarket Tobacco Application	Amendment	03/09/2025
PKG0000885	Test Company A PMTA - Multiple Products	SE - Substantial Equivalence Application	Original	03/08/2025
PKG0000875	Test Company A Meeting Request for Multiple Products	SE - Substantial Equivalence Application	Amendment	03/07/2025
PKG0000865	Test Company A SE - Multiple Products	TC - General Corresponence	Original	03/06/2025

Displaying 5 most recent View All

Create new submission

Choose submission type

PMTA | Premarket Tobacco Product Application

FDA Form 4057

A premarket tobacco product application (PMTA) can be submitted by any person for any new tobacco product seeking an FDA marketing order, under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A PMTA must provide scientific data that demonstrates a product is appropriate for the protection of public health. In order to reach ...

PMTA Amendment | Premarket Tobacco Product Application Amendment

FDA Form 4057A

FDA may request, or an applicant may submit on its own initiative, an amendment to a PMTA containing information that is necessary for FDA complete the review of a pending PMTA. An amendment must include the appropriate form and specify the STN assigned to the original submission and, if submitted other than at FDA's request, the reason for submitting the amendment. An amendment must also include the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant.

SE | Tobacco Substantial Equivalence Report

FDA Form 3965 v.1

A Substantial Equivalence (SE) Report can be submitted by any manufacturer for any new tobacco product seeking an FDA substantially equivalent order, under section 905(j) of the Federal Food, Drug, and Cosmetic (FD&C) Act. A substantially equivalent tobacco product is one that has been found by FDA to have either the same characteristics as a pre…

SE Amendment | Tobacco Substantial Equivalence Report Amendment

FDA Form 3965A

Any amendment must include, among other things, the appropriate form and specify the submission tracking number(s) of the amended SE Report in the subject line.

TC | General Correspondence

FDA Form 3965A/4057A

Information about what a TC General Correspondence is, including why an Industry user would use it and what the requirements are to submit this type of form. Information about what a TC General Correspondence is, including why an Industry user would use it and what the requirements are to submit this type of form. Information about what a…

eSubmitter Upload | Submission Package

Selecting this option allows you to upload the zip file(s) created for a submission package on eSubmitter, the FDA's software available for voluntary use by sponsors, manufacturers, and importers to create a variety of submission types within the drug, blood, device, radiological health, tobacco, animal drug and animal food regulated industries.

Next Cancel

PMTA | Premarket Tobacco Product Application

Name and Description

Submission Name *

Submission Description *

Additional Comments

Create Cancel

Expand All Sections

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0879
Expiration Date: 12/31/2025

Premarket Tobacco Product Application (PMTA) Submission

Marketing without a Marketing Granted Order (MGO) is illegal and may be subject to enforcement.
Please carefully read the instructions below before completing this form.

Premarket Tobacco Product Applications

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

A premarket tobacco product application (PMTA) can be submitted by any person for any new tobacco product seeking an FDA marketing order, under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A PMTA must provide scientific data that demonstrates a product is appropriate for the protection of public health. In order to reach such a decision and to authorize marketing, FDA considers (per section 910(c)(4)), among other things:

- Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available
- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product

Complete the following question and answer form for the Premarket Tobacco Product Application and when all required data has been entered click Submit to deliver the submission to the FDA's Center for Tobacco Products.

For your reference, see the Premarket Tobacco Product Applications guidance for additional information.

Instructions for Completion of the PMTA Form

Form FDA 4057 - Premarket Tobacco Product Application (PMTA) Submission is a required form for applicants to use when submitting a PMTA to FDA. This form and the instructions are solely intended to provide the applicant an organized format to supply information required for submission of a PMTA. For more information on what to include in a PMTA submission, see 21 CFR § 1114.7.

This form is organized into the following sections:

- Applicant Identification
- New Tobacco Product Information
- Submission Information
- Application Contents
- Statements of Compliance with the Federal Food, Drug and Cosmetic (FD&C) Act
- Certification Statements
- Submission Files
- Review and Submit

Each section contains one or more pages that provide details on the specific information being requested along with fields and/or tools to assist you in providing the requested information. To help streamline the data entry process, information you provide is **automatically saved** when entered, and certain pages and fields may be dynamically enabled or disabled depending on the information you have provided earlier in the form. There are also several helpful identifiers that may be associated with a field to help provide further guidance, including:

- **Tooltips:** Indicated by a question mark icon, and provides additional instructions, definitions from the guidance document, and other helpful hints
- **Required Indicators:** Indicated by a red asterisk (*) identifying that the specific field is required before the form can be submitted
- **Validation Errors:** Indicated by descriptive red text located below the field identifying that the data entered in the field has one or more issues

Both Standard and Advanced navigation options are provided to assist in navigating and completing the form, depending on your needs and comfort level:

- **Standard:** Previous and Next buttons are provided at the bottom of each page to guide you sequentially through the relevant sections and pages of this form. Required information on each page must be completed before you can navigate to the subsequent page, making this option well suited for newer users, those unfamiliar with the form, and/or those looking to be guided through the form completion process.
- **Advanced:** A clickable hierarchical outline of the sections and pages in this form is provided on the left side of the screen, allowing you to navigate to any specific section or page in the form at any time, regardless of whether all of the required information has been completed on the current page. This option is well suited for more advanced users, those familiar with the form, and/or those looking to quickly jump to a specific section to provide requested information. Please note, when using the Advanced navigation option, there may be pages and fields that are disabled as they rely on information that you have not yet provided in a previous portion of the form.

The Submission Files section allows you to upload and manage all of the files being submitted with the form. As there are many questions throughout the form that require or allow requested information to be provided in a file, the following tips for using the Submission Files section are recommended (but not required) to help expedite the data entry process:

- **Upload submission files first before filling out the rest of the form:** You can quickly select from your previously uploaded submission files to provide the requested information for each of these questions. If you haven't uploaded submission files previously, you will need to upload a new file each time you come across one of these questions.

The form does not need to be completed in one session, and a draft of your form is saved so that you may return to it at any time to complete it.

The Review and Submit section will show how much required information is left to be provided, as well as identify any information that is recommended to be included/identified. When all of the required information has been provided, you can submit the submission package to the FDA.

Statutory Requirements

Section 910(a)(1) of the FD&C Act - Defines the term "new tobacco product" to mean "(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007."

Section 910(a)(2) of the FD&C Act - Requires premarket review for new tobacco products. There are three pathways to seek premarket authorization, one of which is submitting a Premarket Tobacco Product Application (PMTA).

Paperwork Reduction Act

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB Control Number for this information collection is 0910-0879 and the expiration date is 12/31/2025.

The burden time for this collection of information is estimated to average 35 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

For PRA questions:
PRAStaff@fda.hhs.gov

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

You are in the **Applicant Identification** section. This section requests information regarding the identity of the applicant, and includes the following parts:

Part A: Applicant Information

Part B: Authorized Representative or U.S. Agent Information

Part C: Alternate Point of Contact Information (Optional)

Part D: Manufacturer Information

Part E: Manufacturer/Packing/Sterilization Sites Information (Optional)

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part A: Applicant Information

Part A should include information regarding the applicant for the submission. An applicant may be any person that submits a PMTA who seeks a marketing authorization for a new tobacco product. Part A should be completed for either an organization applicant or an individual applicant, NOT both.

Is the applicant an Organization or an Individual? *

- (●) Organization
- ( ) Individual

Organization Information

Organization Name *
Test Org.

Other Organization Names (if applicable)

Organization FDA-Assigned Facility Establishment Identifier (FEI) Number
_____

Organization D&B DUNS® Number
__-___-____

Country *
UNITED STATES

Street Address Line 1 *
1234 Test St

Street Address Line 2 (Apt., Suite, Bldg., #)

City *
Test

State *
Virginia

Zip Code *
00000-0000

Point of Contact for Organization

First Name *
John

Middle Initial

Last Name *
Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

BACK SAVE & EXIT NEXT

Section I - Applicant Identification

Part A: Applicant Information

Part A should include information regarding the applicant for the submission. An applicant may be any person that submits a PMTA who seeks a marketing authorization for a new tobacco product. Part A should be completed for either an organization applicant or an individual applicant, NOT both.

Is the applicant an Organization or an Individual? *

- ○ Organization
- ◉ Individual

Individual Information

First Name *

Jane

Middle Initial

Last Name *

Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

Country *

ALGERIA

Street Address Line 1 *

1234 Test St.

Street Address Line 2 (Apt., Suite, Bldg., #)

City *

Testing

Province/Territory *

0000000

Postal Code *

0000000

BACK SAVE & EXIT NEXT

Section I - Applicant Identification

Part B: Authorized Representative or U.S. Agent Information

Part B should include information for either an Authorized Representative OR U.S. Agent (for a foreign Applicant). As the Applicant provided in Part A is located within the United States, please provide the information for an Authorized Representative below.

Contact Information for the Authorized Representative

☑ Select if authorized representative is the same as the applicant identified in Part A.

First Name * : John

Middle Initial :

Last Name * : Doe

Generational Suffix :

Professional Suffix :

Position Title :

Email Address :

Phone or Fax Number(s) :

Organization Name * : Test Org.

☑ Select if authorized representative address is the same as the applicant address identified in Part A.

Country * : UNITED STATES

Street Address Line 1 * : 1234 Test St

Street Address Line 2 (Apt., Suite, Bldg., #) :

City * : Test

State * : Virginia

Zip Code * : 00000-0000

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part B: Authorized Representative or U.S. Agent Information

Part B should include information for either an Authorized Representative OR U.S. Agent (for a foreign Applicant). As the Applicant provided in Part A is located outside the United States, please provide the information for a U.S. Agent below.

Contact Information for the U.S. Agent

First Name *
Jon

Middle Initial

Last Name *
Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

Organization Name *
Test Org.

Country *
UNITED STATES

Street Address Line 1 *

Street Address Line 2 (Apt., Suite, Bldg., #)

City *
1234 Test St

State *
Virginia

Zip Code *
00000-0000

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part C: Alternate Point of Contact Information

Part C is an optional space for information for individuals not previously listed in Section I Parts A and/or B. Use the *Add Alternate Point of Contact* button below to add additional alternate points of contact, as needed.

Alternate Point of Contact Information (Optional)

Select alternate: Authorized Representative

First Name * Jane

Middle Initial

Last Name * Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

Organization Name * Testing Org.

Country * UNITED STATES

Street Address Line 1 * 0000 Test St

Street Address Line 2 (Apt., Suite, Bldg., #)

City * Test

State * Virginia

Zip Code * 11111-1111

+ Add Alternate POC

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part D: Manufacturer Information

Part D should include information regarding the Manufacturer for the submission.

Manufacturer Information

☑ Select here if Manufacturer is the same as Applicant identified in Part A

Organization Name * Test Org.

Organization FDA-Assigned Facility Establishment Identifier (FEI) Number _____

Organization D&B DUNS® Number __-___-____

☐ Select here if Manufacturer address is the same as the Applicant address identified in Part A.

Country * UNITED STATES

Street Address Line 1 * 1234 Test St

Street Address Line 2 (Apt., Suite, Bldg., #)

City * Test

State * Virginia

Zip Code * 00000-0000

Point of Contact for Manufacturer

First Name * John

Middle Initial

Last Name * Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part E: Manufacturer/Packaging/Sterilization Sites Information

Part E is an optional space for information for additional manufacturing sites. Use the *Add Manufacturing/Packaging/Sterilization Site* button below to add additional sites, as needed.

Manufacturer/Packaging/Sterilization Sites Information

Select type of site:

Manufacturer

Organization Name *

Tester Org.

Organization FDA-Assigned Facility Establishment Identifier (FEI) Number

Organization D&B DUNS® Number

Division Name (if applicable)

Is the manufacturing/packaging/sterilization site ready for inspection?

- (●) Yes
- ( ) No

Country *

UNITED STATES

Street Address Line 1 *

1010 Test Ln

Street Address Line 2 (Apt., Suite, Bldg., #)

City *

Test

State *

Virginia

Zip Code *

00000-0000

Point of Contact Information for Manufacturer/Packaging/Sterilization Sites

First Name *

Jacob

Middle Initial

Last Name *

Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

+ Add Site

Section II - New Tobacco Product Information

You are in the **New Tobacco Product Information** section. This section requests information for the new tobacco product(s), which must be provided using Form FDA 4057b Premarket Tobacco Product Application Grouping Product Submission Spreadsheet, which is available on the FDA website. Form FDA 4057b allows applicants to submit one PMTA for multiple products—such as e-liquids in varying sizes, nicotine strengths, or flavor combinations—as a grouped submission. Each product in a grouped submission is considered a separate, individual application and must include its own individual environmental assessment. Applicants should keep in mind that the content specific to each product in a grouped submission needs to be clearly specified.

The **Product Form Validator Tool**, which is available on the FDA website, can help validate the data in Form FDA 4057b and confirm the form has been completed consistent with FDA requirements before submitting to FDA. Applicants are not required to use the tool, but using the tool can help reduce the time applicants spend reviewing, correcting, and resubmitting the form. While the tool is designed to help applicants navigate the PMTA submission process, successful validation using the tool does not guarantee that an application contains all elements required for acceptance.

Please upload Form 4057b spreadsheets along with any completion certificates from the Product Form Validator Tool in the Submission Files section.

Expand All Sections

Section III - Submission Information

You are in the **Submission Information** section. This section requests information regarding the submission, and includes the following parts:

Part A: General Submission Information

Part B: Cross-Referenced Information (Optional)

Part C: Referenced Tobacco Product Master File(s) (TPMF) (Optional)

Part D: Formal Meetings Held with FDA Pertaining to the New Product(s) (Optional)

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Submission Information

Part A: General Submission Information

Submission Type

Identify submission type (select one) *

(●) Standard PMTA ( ) Resubmission ( ) Supplemental

Previously Commercially Marketed Product

For products that were previously commercially marketed in the United States, provide the product names and corresponding marketing date(s):

N/A

2497 characters remaining.

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Submission Information

Part B: Cross-Referenced Information (Optional)

Complete Part B if the application includes one or more cross-reference(s) to another PMTA or MRTPA 21 CFR § 1114.7(b), § 1114.15(b), or § 1114.17(b). Supplemental PMTAs and resubmissions may cross-reference content in standard PMTAs. Standard PMTAs should not cross-reference another Standard PMTA or other pending applications with the exception of a pending MRTPA for the same tobacco product. To provide a cross-reference, use the *Add Cross-Referenced Information* button below to add a row to the table to capture the cross-reference information. Within the table, utilize a single row for each cross-reference, and use the *Add Cross-Referenced Information* button below to add additional rows to the table to provide additional cross-references, as needed.

☐ I have filed an MRTPA, but I do not yet have the STN.

Cross-Reference STN *

PM0000000

Is the content relevant to all products within this submission?

◉ Yes
○ No

Information and sections to be referenced (e.g. all sections, sections I-III)

N/A

+ Add Cross Referenced Information

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Submission Information

Part C: Referenced Tobacco Product Master File(s) (TPMF) (Optional)

Complete Part C if the application includes a Tobacco Product Master File (TPMF) 21 CFR § 1114.7 (b)(2). To provide a referenced TPMF, use the *Add Referenced TPMF* button below to add a row to the table to capture the referenced TPMF information. Within the table, utilize a single row for each TPMF, and use the *Add Referenced TPMF* button below to add additional rows to the table to provide additional reference TPMFs, as needed.

TPMF Owner

John Doe

TPMF STN (assigned by FDA)

PM0000000

Is the content applicable to all products within the submission?

- (●) Yes
- ( ) No

Information and sections to be referenced

N/A.

Right of reference included?

- (●) Yes
- ( ) No

+ Add Referenced TPMF

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Submission Information

Part D: Formal Meetings Held with FDA Pertaining to the New Product(s) (Optional)

Complete Part D if FDA and the applicant held one or more meetings related to the new product(s). This can include meetings for study design, earlier versions of the product, etc. To provide a Formal Meeting, use the *Add Formal Meeting* button below to add a row to the table to capture the meeting information. Within the table, utilize a single row for each meeting, and use the *Add Formal Meeting* button below to add additional rows to the table to list additional meetings, as needed.

Submission STN

PM0000000

Meeting Held Date

10-01-2024

Is the meeting relevant to all products within this submission?

- (●) Yes
- ( ) No

+ Add Formal Meeting

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - Application Contents

You are in the **Application Contents** section, which is intended to help applicants organize their submission per 21 CFR § 1114.7, and includes the following parts:

Part A: Administrative Content

Part B: Labeling and Marketing Plans

Part C: Inspections

Part D: Scientific Content

Each part of the Application Contents section contains a checklist of relevant documents that are required or recommended for inclusion with your submission. For each item included in your submission, select the corresponding checkbox in the list and provide the location of the document. For example, the file name, document name, and page number. Select all that apply. All documents should be uploaded in the Submission Files section.

Section IV - Application Contents

Part A: Administrative Content

Document Checklist for Administrative Content

This application contains the following Administrative Content items (select all that apply and indicate file name and location of application content). All documents should be uploaded in the Submission Files section.

☑ **Cover Letter**

Location (Comments)

//

☑ **Comprehensive Index[1] and Table of Contents[1]**

Location (Comments)

//

☑ **English[1] Translations for Non-English Information**

Location (Comments)

//

☐ **Request for FDA to refer PMTA to TPSAC[1]**

Location (Comments)

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - Application Contents

Part B: Labeling and Marketing Plans

Document Checklist for Labeling and Marketing Plans

This application contains the following Labeling and Marketing Plan items (select all that apply and indicate file name and location of application content). All documents should be uploaded in the Submission Files section.

☐ **Specimens of all Proposed Labeling[1]**

Location (Comments)

☐ **Description of Marketing Plans[1]**

Location (Comments)

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

☐ Expand All Sections

Section IV - Application Contents

Part C: Inspections

Document Checklist for Inspections

This application contains the following Inspection items (select all that apply and indicate file name and location of application content). All documents should be uploaded in the Submission Files section.

☐ **Location and Contact Information for Each Location Subject to Potential Inspection**

Location (Comments)

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - Application Contents

Part D: Scientific Content

Document Checklist for Scientific Content

This application contains the following Scientific Content items (select all that apply and indicate file name and location of application content). All documents should be uploaded in the Submission Files section.

☐ **General Information**[1]

Location (Comments)

☐ **Descriptive Information**[1]

Location (Comments)

☐ **Product Samples**[2]

Location (Comments)

☐ **Statement of Compliance with 21 CFR part 25**[1]

Location (Comments)

☐ **Summary**[1]

Location (Comments)

☐ **Product Formulation**[1]

Location (Comments)

☐ **Manufacturing**[1]

Location (Comments)

☐ **Literature Search**[1]

Location (Comments)

☐ **Organized References**

Location (Comments)

☐ **Health Risk Investigations**[1]

Location (Comments)

☐ **Study Reports**[1]

Location (Comments)

Expand All Sections

Section V – Statements of Compliance with the Federal Food, Drug and Cosmetic (FD&C) Act

You are in the **Statements of Compliance** section. This section requests descriptions of how the PMTA satisfies content requirements of section 910(b)(1) of the FD&C Act and how marketing the new tobacco product would be appropriate for the protection of public health. It includes the following pages:

i. §910(b)(1) Requirements
ii. Protection of Public Health

§910(b)(1) Requirements

Provide information for how the application meets the requirements and addresses the question(s) in each of the statements according to the requirements section 910(b)(1) of the FD&C Act as required by 21 CFR § 1114.7(c)(10) and (11). Your descriptions should address:

- Full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products.
- Full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product.
- Full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product.
- An identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard.
- Specimens of the labeling proposed to be used for such tobacco product.
- Such other information relevant to the subject matter of the application as the Secretary may require.

Protection of Public Health

Provide a brief description of how marketing the new tobacco product would be appropriate for the protection of public health as determined with respect to the population as a whole, including users and non-users of the tobacco product, and taking into account:

- The increased or decreased likelihood that existing users of tobacco products will stop using such products.
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

Expand All Sections

Section V - Statements of Compliance with the Federal Food, Drug and Cosmetic (FD&C) Act

i. §910(b)(1) Requirements

Provide a brief description of how the PMTA satisfies content requirements of section 910(b)(1) of the FD&C Act in the space below: *

N/A

1497 characters remaining.

BACK SAVE & EXIT NEXT

Expand All Sections

Section V - Statements of Compliance with the Federal Food, Drug and Cosmetic (FD&C) Act

ii. Protection of Public Health

Provide a brief description of how marketing the new tobacco product would be appropriate for the protection of public health as determined with respect to the population as a whole including users and non-users of the tobacco product, and taking into account:*

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

N/A

1497 characters remaining.

BACK SAVE & EXIT NEXT

Expand All Sections

Section VI – Certification Statements

You are in the **Certification Statements** section. Applications must contain the following certifications, as appropriate for the specific type of PMTA, with the appropriate information inserted, as described in each parenthetical, signed by an authorized representative of the applicant. You will be presented with the appropriate certification statement(s) to complete based on the specific type of PMTA identified in Section III Part A, as follows:

i. Certification Statement for Standard PMTAs
ii. Modified Tobacco Product Certification for Supplemental PMTAs
iii. Same Product Certification for Resubmissions
iv. Different Product Certification for Resubmissions
v. Financial Interest and Arrangements of Clinical Investigators Certification Statement (for all submission types)

For each applicable certification statement, provide all of the requested information on the page, which will then generate a completed certification statement that must be signed by the authorized representative.

BACK SAVE & EXIT NEXT

Section VI - Certification Statements

i. Certification Statement for Standard PMTAs

Certification statement for standard PMTAs is appropriate when submitting a standard PMTA.

Insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A.

Standard PMTA Certifications

Standard Pmta Certification

Name of Responsible Official *

Jane Doe

Applicant Name

Test Org.

I, **Jane Doe**, on behalf of the applicant, **Test Org.**, 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 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.

Digital Signature *

Sign above

Logged in User Account:	Digitally Signed For:	Digitally Signed On:
Simmons_Kelvin@bah.com	Jane Doe	October 4th 2024, 1:45:10 pm

+ Add Standard PMTA Certification

Section VI - Certification Statements

ii. Modified Tobacco Product Certification for Supplemental PMTAs

The **Modified Tobacco Product Certification for Supplemental PMTAs** is appropriate when submitting a supplemental PMTA. To include this certification statement in your submission, provide the requested information below, which will generate a certification statement that must then be signed by the authorized representative.

The applicant identified in Section I Part A has already been populated below. For Name of Responsible Person, select the authorized representative below as identified in Section I Part B or Part C who is signing the certification. Provide the individual new product(s) names(s), a description of each modification, and the name and STN of the previously submitted PMTA where appropriate.

If submitting multiple products, it is recommended a separate certification is submitted for each product. Use the *Add Modified Tobacco Product Certification for Supplemental PMTAs* button below to add additional certification statements, as needed.

Modified Tobacco Product Certification for Supplemental PMTAs

Name of Responsible Official * : John Doe

Applicant Name : Test Org.

New Tobacco Product Name * : Product A

141 characters remaining.

STN of Previously submitted PMTA(s) * : PM000000

142 characters remaining.

Product Modifications * : N/A

497 characters remaining.

Original Tobacco Product * : Product B

141 characters remaining.

I, **John Doe**, on behalf of the applicant **Test Org.**, certify that **Product A** has a different **N/A** than **Product B** described in **PM000000** but is otherwise identical to **Product B** I certify that **Test Org.** understands this means there is no other modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product. I also certify that **Test Org.** will maintain all records that substantiate the accuracy of this application, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, 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.

Digital Signature *

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Simmons_Kelvin@bah.com	John Doe	October 7th 2024, 4:29:34 pm

+ Add Modified Tobacco Product Certification for Supplemental PMTAs

Expand All Sections

Section VI - Certification Statements

iii. Same Tobacco Product Certification for Resubmission

The **Same Tobacco Product Certification for Resubmissions** is appropriate when submitting a resubmission PMTA where the product is unchanged, and the applicant is addressing deficiencies outlined in the marketing denial order (MDO). To include this certification statement in your submission, click the *Add Same Tobacco Product Certification for Resubmissions* button and provide the requested information below, which will generate a certification statement that must then be signed by the authorized representative.

The applicant identified in Section I Part A has already been populated below. For Name of Responsible Person, select the authorized representative below as identified in Section I Part B or Part C who is signing the certification. Provide the individual new product(s) names(s), and the STN of the previously submitted PMTA where appropriate in the statement. Use the *Add Same Tobacco Product Certification for Resubmissions* button below to add additional certification statements, as needed.

Same Tobacco Product Certification for Resubmission

Name of Responsible Official * : John Doe

Applicant Name : Test Org.

New Tobacco Product Name * : Product C

141 characters remaining.

STN of Previously Submitted PMTA(s) * : PM0000000

141 characters remaining.

I, **John Doe**, on behalf of the applicant, **Test Org.**, certify that this submission for **Product C** responds to all deficiencies outlined in the marketing denial order issued in response to **PM0000000** and the new tobacco product described herein is identical to the product described in the previously submitted PMTA. I certify that **Test Org.** understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature. I also certify that **Test Org.** will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company'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.

Digital Signature *

Sign above

Logged in User Account:	Digitally Signed For:	Digitally Signed On:
Simmons_Kelvin@bah.com	John Doe	October 7th 2024, 4:32:02 pm

+ Add Same Tobacco Product Certification for Resubmissions

Section VI - Certification Statements

iv. Different Tobacco Product Certification for Resubmission

The **Different Tobacco Product Certification for Resubmissions** is appropriate when submitting a resubmission PMTA where the product is a modification of the previously submitted PMTA that results from changes necessary to address the deficiencies outlined in the marketing denial order (MDO). To include this certification statement in your submission, click the *Add Different Tobacco Product Certification for Resubmissions* button and provide the requested information below, which will generate a certification statement that must then be signed by the authorized representative.

The applicant identified in Section I Part A has already been populated below. For Name of Responsible Person, select the authorized representative below as identified in Section I Part B or Part C who is signing the certification. Provide the individual new product(s) names(s), the name and the STN of the previously submitted PMTA, and a description of each modification where appropriate.

If submitting multiple products, it is recommended a separate certification is submitted for each product. Use the *Add Different Tobacco Product Certification for Resubmissions* button below to add additional certification statements, as needed.

Different Tobacco Product Certification for Resubmission

Name of Responsible Official *

John Doe

Applicant Name

Test Org.

New Tobacco Product Name *

Product D

141 characters remaining.

STN of Previously Submitted PMTA(s) *

PM0000000

141 characters remaining.

Product Modifications *

Product Update

486 characters remaining.

Original Tobacco Product *

Product S

141 characters remaining.

I, **John Doe** on behalf of **Test Org.** certify that this submission for **Product D** responds to all deficiencies outlined in the marketing denial order issued in response to **PM0000000** and the new tobacco product described herein has a different **Product Update** than **Product S** described in **PM0000000** but is otherwise identical to **Product S** described in **PM0000000**. I certify that **Test Org.** understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product, except for the **Product Update**. I also certify that **Test Org.** will maintain all records that substantiate the accuracy of this statement and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company'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.

Digital Signature *

Sign above

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Simmons_Kelvin@bah.com	John Doe	October 7th 2024, 4:34:02 pm

+ Add Different Tobacco Product Certification for Resubmission

Expand All Sections

Section VI - Certification Statements

v. Financial Interest and Arrangements of Clinical Investigators Certification

Financial Interest and Arrangements of Clinical Investigators Certification Statement is appropriate when submitting any type of PMTA and must be included if your application includes any type of study in support of this application. This certification covers all actions taken to ensure the reliability of the study.

Insert the name of the authorized representative as identified in Section I Part B or Part C, and the name of the organization being represented as identified in Section I Part A.

Financial Interest and Arrangements of Clinical Investigators Certification Statement is appropriate when submitting any type of PMTA and must be included if your application includes any type of study in support of this application. This certification covers all actions taken to ensure the reliability of the study. Insert the name of the authorized representative as identified in Section I Part B or Part C, and the name of the organization being represented as identified in Section I Part A.

Financial Certification

Name of Responsible Official *

Jane Doe

Name of Company

Test Org.

I, **Jane Doe**, on behalf of **Test Org.**, certify that there are no financial conflicts of interest or have included documentation fully disclosing any potential financial conflicts of interest required by 21 CFR § 1114.7(k)(3)(ii).

Conflicts of interest: *

- (●) No, there are no financial conflicts of interest
- ( ) Yes, there are financial conflicts of interest and documentation is provided (please specify in the table of contents where the documentation is located)

Digital Signature *

Sign above

Logged in User Account: Simmons_Kelvin@bah.com	**Digitally Signed For: Jane Doe**	**Digitally Signed On: October 4th 2024, 1:46:10 pm**

+ Add Financial Interest and Arrangements of Clinical Investigators Certification Statement

BACK SAVE & EXIT NEXT

Expand All Sections

Submission Files

Select file(s) to upload

Allowed file types:

.TXT,.BMP,.CSS,.CML,.CSV,.DTD,.XLS,.XLSX,.XML,.XSL,.GIF,.HTM,.HTML,.JPG,.JPEG,.KML,.MOL,.MPG,.MPEG,.MP3,.MP4,.PDF,.PNG,.MOV,.XPT,.XPORT,.SVG,.SDF,.WMV,.WAV,.XSD

File Name	Size

Drop files to attach, or browse

Submission Files

Rows: 25

Search table content

Actions	File Name	Descriptive Title	File Size	Status

Columns Filter(s)

0 to 0 of 0 Page 0 of 0

BACK SAVE & EXIT NEXT

Expand All Sections

Review and Submit

You have reached the end of this submission. You may now submit your submission to CTP in order to fulfill your requirements. Submission via the CTP Portal NextGen provides secure transmission and enables the FDA to provide you with an automated acknowledgment of receipt.

If you would like to submit this submission at this time, please click the Submit button below. If any required data is missing, the submission will not be submitted and you will be prompted to provide the missing data. Please ensure that all required questions are completed and all applicable documents have been attached within the submission.

You may also save and exit this submission to return to it at a later time if you do not wish to submit it now. To do so, simply click Save and Exit below. To re-open this submission after exiting, navigate to the Submissions > Draft Submission Packages landing page, click the actions button next to this submission package in the table and select Edit.

If you would like to prepare another submission to fulfill other FDA requirements, please select the Create New Submission button at the top of the page to begin compiling a new submission and be sure to select the appropriate submission type.

Submit Form

BACK SUBMIT NEXT

Submission Package Received

Your submission package has been delivered to the Center for Tobacco Products (CTP) for additional processing. Please refer to the Sent Submission Packages page at any time to view the status of your submission package.

A PDF report has been generated for your records detailing the contents of your submission package. This report is available for download by clicking on the Download Submission Package Report button below, and may also be accessed at any time from the Sent Submission Packages page.

Once CTP completes processing of your submission package, CTP will assign a Submission Tracking Number (STN) for each submission created from the package and will notify your organization that the submission(s) has been published and is available to view in the CTP Portal NextGen from the Published Submissions page. Please note this does not constitute review of the submission.

At this time, if you would like to prepare another submission package to fulfill other FDA requirements, please select the Create New Submission button to begin compiling a new submission package and be sure to select the appropriate submission type.

If you have any CTP Portal NextGen related technical questions or need assistance, please contact us at CTPeSub@fda.hhs.gov or (877) 287-1373. To assist us in helping you, please include your organization, upload date, and the submission package ID for your submission in all correspondence.

Exit Download Submission Package Report View Sent Submission Packages