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

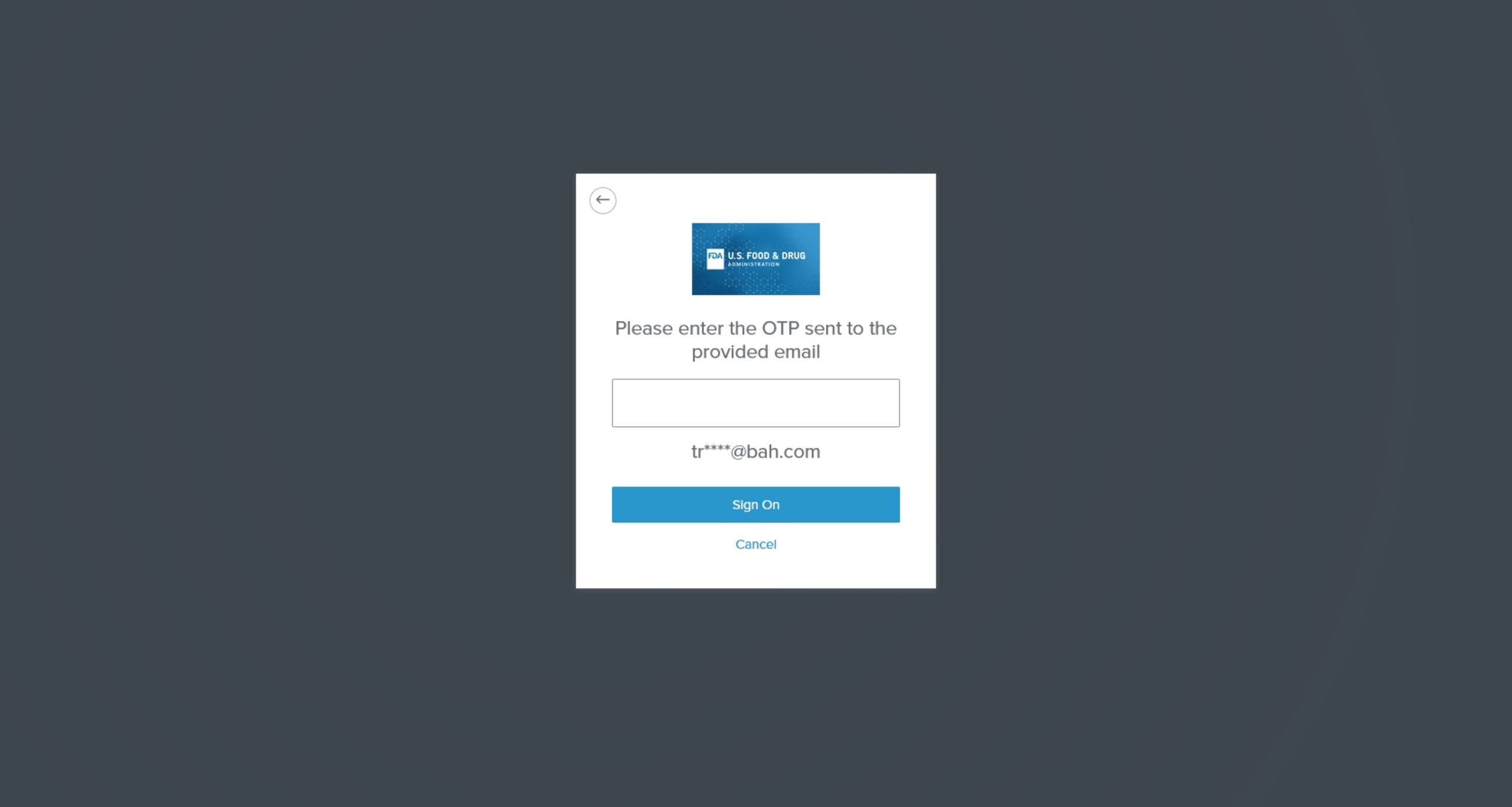
EMAIL

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

SE | Tobacco Substantial Equivalence Report

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. 0910-0673
Expiration Date: XX/XX/20XX

Tobacco Substantial Equivalence (SE) Report Submission

Marketing a New Tobacco Product without a Substantially Equivalent Order is illegal and may be subject to enforcement.[1]
Please carefully read the instructions located in the Appendix before completing this form.

Tobacco Substantial Equivalence (SE) Report Submission

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 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 predicate product or has different characteristics than the predicate tobacco product but the Substantial Equivalence Report demonstrates that the new product does not raise different questions of public health. A predicate tobacco product is one that was commercially marketed (other than for test marketing) in the United States as of Feb. 15, 2007, or is a product previously found to be substantially equivalent by FDA.

Complete the following question and answer form for the Tobacco Substantial Equivalence Report Submission 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 Tobacco Substantial Equivalence Report Submission guidance for additional information.

Provisional SE Tobacco Products

New tobacco products commercially marketed after February 15, 2007 but before March 22, 2011 with an SE Report submitted by March 22, 2011 are known as provisional SE tobacco products—these may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent.

Instructions for Completion of the SE Form

Form FDA 3965 – Tobacco Substantial Equivalence Report Submission is a required form for applicants to use when submitting an SE Report to FDA. This form and the instructions for use are solely intended to provide the applicant an organized format to supply information required for submission of a Substantial Equivalence (SE) Report. For more information on what to include in an SE submission, see 21 CFR § 1107.18.

This form is organized into the following sections:

- Applicant Identification
- New Product(s) Information
- Predicate Product(s) Eligibility
- Submission Information
- Application Contents Checklist
- 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 Substantial Equivalence (SE) Report.

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 0910-0673 and the expiration date is XX/XX/20XX.

The burden time for this collection of information is estimated to average 45 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

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.

Identify whether the applicant is a manufacturer OR importer?[2] *

- (●) Manufacturer
- ( ) Importer

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

Expand All Sections

BACK SAVE & EXIT NEXT

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.

Identify whether the applicant is a manufacturer OR importer?[2] *

- (●) Manufacturer
- ( ) Importer

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 *

Test

Province/Territory *

Territory_Test

Postal Code *

0000000000

BACK SAVE & EXIT NEXT

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 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

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 * : 1234 Test St

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

City * : Test

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:

First Name *

Middle Initial

Last Name *

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

Organization Name *

Country *

Street Address Line 1 *

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

City *

Province/Territory *

Postal Code *

+ Add Alternate POC

BACK SAVE & EXIT NEXT

Section I - Applicant Identification

Part D: Manufacturer Information

Part D should include information for both the Manufacturer of the new tobacco product as well as the Manufacturer of the predicate tobacco product. Use the *Add Manufacturer* button below to add additional manufacturers of the new and predicate tobacco products, as needed.

Expand All Sections

New and Predicate Product Manufacturer

New Product(s) Manufacturer

The below fields apply to the Manufacturer of the NEW tobacco product. Only complete this section if the Manufacturer of the new tobacco product is different from the Applicant identified in Section I Part A. If the same, select the checkbox to indicate they are the same and continue to the Predicate Product(s) Manufacturer section below.

- [x] 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 * : _____-____

Point of Contact for New Product(s) Manufacturer

First Name * : Jane

Middle Initial :

Last Name * : Doe

Generational Suffix :

Professional Suffix :

Position Title :

Email Address :

Phone or Fax Number(s) :

+ Add Phone/Fax

Predicate Product(s) Manufacturer

- [x] Select here if Predicate Manufacturer is the same as Applicant identified in Part A and proceed to next page
- [ ] Select here if Predicate Manufacturer is the same as New Product(s) Manufacturer identified above and proceed to next page

Organization Name :

- [ ] Select here if Predicate Manufacturer address is the same as the Applicant address identified in Part A
- [ ] Select here if Predicate Manufacturer address is the same as the New Product(s) Manufacturer's address identified above

Country :

Street Address Line 1 :

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

City :

Province/Territory :

Postal Code :

Point of Contact for Predicate Product(s) Manufacturer

First Name : John

Middle Initial :

Last Name : Doe

Generational Suffix :

Professional Suffix :

Position Title :

Email Address :

Phone or Fax Number(s) :

+ Add Phone/Fax

+ Add Manufacturer

Section I - Applicant Identification

Part E: Manufacturer/Packaging/Sterilization Sites Information

Part E is an optional space to provide additional site information for the raw materials and/or components used in the manufacture of the finished new and/or predicate products (e.g., contract, processor of primary material, component fabricator, labeling service provider, repacking by third party). Use the *Add Manufacturer/Packaging/Sterilization Site* button below to add additional sites, as needed.

Manufacturer/Packaging/Sterilization Sites Information

Select type of site:

Manufacturer

Alternate manufacturing site for:

Organization Name *

Test 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 *

1234 Test St

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

City *

Test

State *

Virginia

Zip Code *

Point of Contact Information for Manufacturer/Packaging/Sterilization Sites

First Name *

John

Middle Initial

Last Name *

Doe

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

+ Add Manufacturer/Packaging/Sterilization Site

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - New Product(s) Information

You are in the **New Product(s) Information** section. This section requests information for the new tobacco product(s), which must be provided using Form FDA 3965b - Tobacco Substantial Equivalence Product Grouping Spreadsheet, which is available on the FDA website.

The **Product Form Validator Tool**, which is available on the FDA website, can help validate the data in Form FDA 3965b 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 SE submission process, successful validation using the tool does not guarantee that an application contains all elements required for acceptance.

Please upload Form FDA 3965b spreadsheets along with any completion certificates from the Product Form Validator Tool in the Submission Files section.

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Predicate Product(s) Eligibility

You are in the **Predicate Product(s) Eligibility** section. This section requests information regarding the predicate product(s), and includes the following parts:

Part A: Predicate Product(s) Status

Part B: Predicate Product Evidence

Part C: Statement of Affirmation

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Predicate Product(s) Eligibility

Part A: Predicate Product(s) Status

Indicate how the predicate product(s) are eligible to serve as a predicate product for the new product(s). Select all statements below that apply to the predicate tobacco product(s). Complete all necessary information for each statement.

☑ **Previously Found SE**

- If selected, skip Section III Parts B and C.

☐ **PTP Determined**

- If selected, complete Section III Part C only.

☐ **Claimed PTP**

- If selected, complete Section III Parts B and C.

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Predicate Product(s) Eligibility

Part B: Evidence of Commercial Marketing as of February 15, 2007

Based on your response in Part A that the predicate products were not previously submitted for PTP review and were not previously found to be substantially equivalent, please provide information regarding the evidence of commercial marketing below.

Evidence of Commercial Marketing

Type of Evidence (e.g., Invoice)

Date of Evidence

Evidence Identifier (e.g., Invoice Number)

Commercial Information (e.g., UPC code, product description, item number)

Predicate Product Name(s)

Country

Street Address Line 1

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

City

Province/Territory

Postal Code

+ Add Evidence of Commercial Marketing

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section III - Predicate Product(s) Eligibility

Part C: Statement of Affirmation

Applications using PTP products as predicates must include the PTP claim statement. This must be from a responsible official who has knowledge of the test marketing status of the tobacco product in the United States as of February 15, 2007, and has authority to make such a statement. For the following section, insert the name of the responsible official and the name(s) of the predicate product(s).

Certification Statement Regarding Availability of Health Information

Name of Responsible Official

John Doe

Name of Predicate Tobacco Product(s)

Test Product 1

I, **John Doe**, confirm that the predicate tobacco product(s) listed above was/were commercially marketed (other than for test marketing) in the United States as of February 15, 2007.

Digital Signature *

Sign above

Logged in User Account:	Digitally Signed For: [object Object]	Digitally Signed On: October 7th 2024, 7:14:06 pm

+ Add Statement of Affirmation

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - 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

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - Submission Information

Part A: General Submission Information

Applicants may bundle groups of SE Reports for their new product(s) in the same product category and subcategory where the proposed modifications are the same. For grouped submissions, the application type must be the same and the proposed modification(s) to the new tobacco products (as compared to the predicate tobacco product[s]) should be similar. If application type is not the same and/or proposed modification are not similar, submit a separate Form FDA 3965.

Type of Application[2] *

◯ Same Characteristics Reports ◯ Different Characteristics Reports

Submission Summaries[2]

Proposed modification(s) to the tobacco product(s) (as compared to the predicate tobacco product[s])[2]

- ☐ Tobacco Blend
- ☐ Design
- ☐ Materials
- ☐ Container Closure System
- ☐ Heating Source
- ☐ Product Quantity
- ☐ Composition
- ☐ Ingredients (Specify below)
- ☐ Other (Specify below)

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - Submission Information

Part B: Cross-Referenced Information (Optional)

Complete Part B if the application includes one or more cross-reference(s) to a standalone PTP submission or authorized SE submission other than the predicate product listed in Form FDA 3965b. SE Reports should not cross-reference other pending SE applications. 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-Referenced STN *

_____

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)

+ Add Cross Referenced Information

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - 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

TPMF STN (assigned by FDA)

_____

Is the content applicable to all products within the submission?

- Yes
- No

Information and sections to be referenced

Right of reference included?

- Yes
- No

+ Add Referenced TPMF

BACK SAVE & EXIT NEXT

Expand All Sections

Section IV - 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

Meeting Held Date

Is the meeting relevant to all products within this submission?

- (●) Yes
- ( ) No

+ Add Formal Meeting

BACK SAVE & EXIT NEXT

Expand All Sections

Section V - Application Contents Checklist

You are in the **Application Contents Checklist** section, which is intended to help applicants organize their submission per 21 CFR § 1107.18, and includes the following parts:

Part A: Administrative Content

Part B: Product Information

Part C: Health and Research

Part D: Comparisons

Part E: Environmental Considerations

Each part of the Application Contents Checklist 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.

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section V - Application Contents Checklist

Part A: Administrative Content

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[2] and Table of Contents[2]**

Location (Comments)

☐ **Unique Identification of New Tobacco Product(s) and Predicate Tobacco Product(s) (Form FDA 3965b - Substantial Equivalence Product Application Group Product Submission Spreadsheet)[2]**

Location (Comments)

☐ **English Translations for Non-English Information[2]**

Location (Comments)

BACK SAVE & EXIT NEXT

Expand All Sections

Section V - Application Contents Checklist

Part B: Product Information[2]

Checklist for Product Information

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

☐ **List of Ingredients**

Location (Comments)

☐ **Information on Manufacturing Process**

Location (Comments)

☐ **Statement of Compliance with Applicable Tobacco Product Standards**

Location (Comments)

Expand All Sections

Section V - Application Contents Checklist

Part C: Health and Research[2]

Checklist for Health and Research (select only one)

Select only one checkbox in Part C to indicate whether the application contains a Health Information Summary or Health Information Statement, as required by 21 CFR 1107.18(j). All documents should be uploaded in the Submission Files section.

☐ **Health Information Summary**

Location (Comments)

☐ **Health Information Statement**

Location (Comments)

BACK SAVE & EXIT NEXT

Expand All Sections

Section V - Application Contents Checklist

Part D: Comparisons[2]

Checklist for Comparisons (New vs Predicate Tobacco Product)

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

Product Design

Location (Comments)

Heating Source

Location (Comments)

Composition

Materials

Ingredients, tobacco

Location (Comments)

Ingredients, non-tobacco

Location (Comments)

Other Features

HPHCs

Other (specify below)

Location (Comments)

Stability

Location (Comments)

Comparison to Original Predicate Tobacco Product(s) (Select only if the predicate product was previously found SE)

Location (Comments)

BACK SAVE & EXIT NEXT

Expand All Sections

Section V - Application Contents Checklist

Part E: Environmental Considerations[2]

Checklist for Environmental Considerations (select only one)

This application contains one of the following Environmental Considerations items (select only one). All documents should be uploaded in the Submission Files section.

☐ **Environmental Assessment**

Location (Comments)

☐ **Claim for Categorical Exclusion**

Location (Comments)

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section VI – Certification Statements

You are in the **Certification Statements** section. This section will present you with the appropriate certification statement(s) to complete based on the specific type of SE Report identified in Section IV Part A and the Health Information option selected in Section V Part C, as follows:

i. Certification Statement for SE Report (for all SE Reports)
ii. Certification Statement for Same Characteristics SE Report (for Same Characteristics SE Reports)
iii. Certification Statement Regarding Availability of Health Information (for SE Reports choosing to make Health Information available upon request)

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

BACK SAVE & EXIT NEXT

Expand All Sections

Section VI - Certification Statements

i. Certification Statement for SE Report

The **Certification Statement for SE Report** is required for all SE Reports. 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 Name of Application has already been populated below with the applicant identified in Section I Part A.
- For Name of Responsible Official, select the authorized representative or U.S. agent below as identified in Section I Part B or Part C who is signing the certification.

Use the *Add Certification Statement for SE Report* button below to add additional certification statements, as needed.

Certification Statement for SE Report

Name of Responsible Official *

Other

Other *

Test

Name of Applicant

Test Org

I, **Test**, on behalf of the applicant, **Test Org**, hereby certify that **Test Org** will maintain all records to substantiate the accuracy of this SE Report for the period of time required in 21 CFR 1107.58 and ensure that such 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	Test	October 7th 2024, 5:54:01 pm

+ Add Certification Statement for SE Report

BACK SAVE & EXIT NEXT

Section VI - Certification Statements

ii. Certification Statement for Same Characteristics SE Report

The **Certification Statement for Same Characteristics SE Report** is appropriate when submitting a Same Characteristics SE Report and choosing to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate products. To include this certification statement in your submission, click the *Add Certification Statement for Same Characteristics SE Report* button and provide the requested information below, which will generate a certification statement that must then be signed by the authorized representative.

- The Name of Company has already been populated below with the applicant identified in Section I Part A.
- For Name of Responsible Official, select the authorized representative below as identified in Section I Part B or Part C who is signing the certification.
- Provide the name(s) of the individual new and predicate product(s), as identified in Section II.
- Provide a description of the modifications, as identified in Section IV Part A.

If submitting a grouped submission, a certification statement is needed for each new product. Use the *Add Certification Statement for Same Characteristics SE Report* button below to add additional certification statements, as needed.

Certification Statement for Same Characteristics SE Report

Name of Responsible Official *

John Doe

Name of Company

Test Org

Name of New Tobacco Product *

Test Product A

136 characters remaining.

Name of Predicate Tobacco Product *

Test Product B

136 characters remaining.

Describe Modification(s) *

Product Test

487 characters remaining.

I, **John Doe**, on behalf of **Test Org**, certify that **Test Product A** has the following modification(s) as compared to **Test Product B** due to the following modification(s): **Product Test** . Aside from these modifications, the characteristics of **Test Product A** and **Test Product B** are identical. I certify that **Test Org** understands this means there is no other modification to the materials, ingredients, design features, heating source, or any other feature. I also certify that **Test Org** will maintain records to support the comparison information in 21 CFR 1107.19 that substantiate the accuracy of this statement for the period of time required in 21 CFR 1107.58, and ensure that such records remain readily available to FDA upon request.

Digital Signature *

Sign above

Logged in User Account:	Digitally Signed For:	Digitally Signed On:
Simmons_Kelvin@bah.com	John Doe	October 7th 2024, 5:54:58 pm

+ Add Certification Statement for Same Characteristics SE Report

Expand All Sections

BACK SAVE & EXIT NEXT

Section VI - Certification Statements

iii. Certification Statement Regarding Availability of Health Information

The **Certification Statement Regarding Availability of Health Information** is appropriate when choosing to make health information available upon request as per 21 CFR 1107.18(j)(2) rather than including a health information summary with their SE Report. To include this certification statement in your submission, click the *Add Certification Statement Regarding Availability of Health Information* button and provide the requested information below, which will generate a certification statement that must then be signed by the authorized representative.

- For Name of Responsible Official, select the authorized representative below as identified in Section I Part B or Part C who is signing the certification.
- The Position Held in Company by Person Required to Submit the SE Report will be populated with the position title identified in Section I Part B or Part C for the selected authorized representative
- The Name of Company will be populated with the organization name identified in Section I Part B or Part C for the selected authorized representative

Use the *Add Certification Statement Regarding Availability of Health Information* button below to add additional certification statements, as needed.

Certification Statement Regarding Availability of Health Information

Name of Responsible Official *

John Doe

Position Held in Company by Person Required to Submit the SE Report *

Scientist

141 characters remaining.

Name of Company *

Test Org

142 characters remaining.

I, **John Doe**, certify that, in my capacity as **Scientist** of **Test Org**, I will make available, upon request, the information identified in 21 CFR 1107.18(j)(3) within 30 calendar days of a request.

Digital Signature *

Sign above

Logged in User Account:	Digitally Signed For:	Digitally Signed On:
Simmons_Kelvin@bah.com	John Doe	October 7th 2024, 5:56:06 pm

+ Add Same Tobacco Product Certification for Resubmission

Expand All Sections

BACK SAVE & EXIT NEXT

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	Date Uploaded
					mm / dd / yyyy

Columns Filter(s)

0 to 0 of 0 Page 0 of 0

BACK SAVE & EXIT NEXT

BACK SUBMIT 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