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

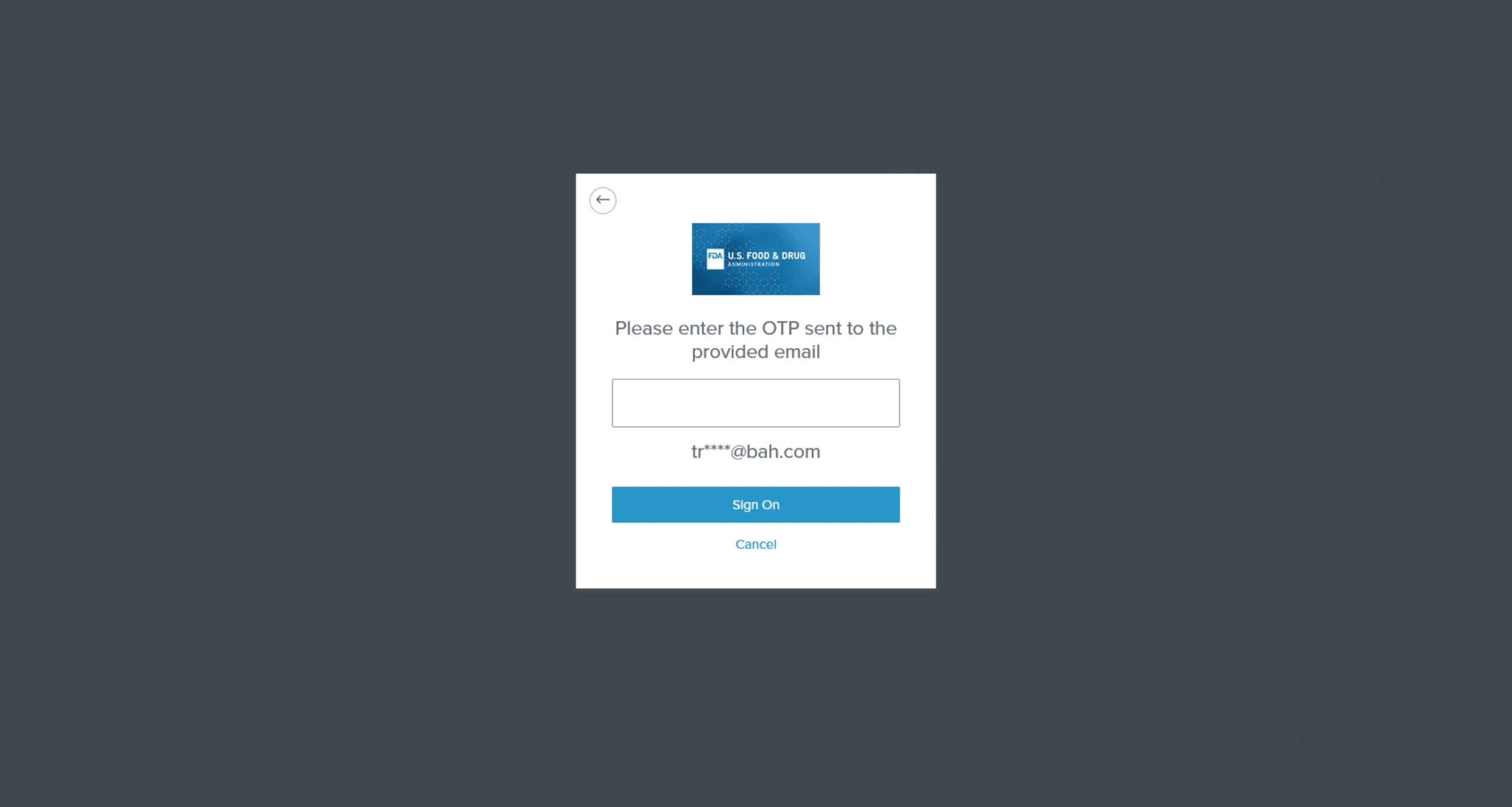
EMAIL

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 Amendment | Tobacco Substantial Equivalence Report Amendment

Name and Description

Submission Name *

Submission Description *

Additional Comments

Create Cancel

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 Amendment Submission

Marketing a New Tobacco Product without a Marketing Granted Order (MGO) is illegal and may be subject to enforcement.[1]
Please carefully read the instructions below before completing this form.

Tobacco Substantial Equivalence (SE) Report Amendments

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).

When submitting a SE Report, applicants are expected to submit all required information, however, additional information may be needed for FDA to complete its review of a SE Report, so applicants are allowed to submit amendments to a pending application.

FDA may, at any time after it receives and before it acts on an application, request an applicant submit additional information so the agency can complete its review of a SE Report. Similarly, an applicant may choose to submit an amendment with additional information on their own. Amendments may include information like a new study that is relevant to the SE Report, clarifications, or changes/updates to information submitted in the original SE Report.

Complete the following question and answer form for the Tobacco Substantial Equivalence (SE) Report Amendment 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 Substantial Equivalence guidance for additional information.

Instructions for Completion of the SE Amendment Form

Form FDA 3965a - Tobacco Substantial Equivalence (SE) Amendment Submission is a required form for applicants submitting SE Amendments 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 Substantial Equivalence (SE) Report Amendment.

This form is organized into the following sections:

- Applicant Identification
- Amendment Information
- 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 0910-0673 and the expiration date is XX/XX/20XX.

The burden time for this collection of information is estimated to average 10 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff

For PRA questions:
PRAStaff@fda.hhs.gov

Citations

The following citations are referenced throughout the form:

[1] A tobacco product that was introduced or delivered for introduction into interstate commerce after February 15, 2007, and prior to March 22, 2011, and for which a Substantial Equivalence (SE) Report was submitted by March 22, 2011, (Provisional SE Reports) may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent.

[2] Required content and format as per 1107.18.

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification[2]

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

Part A: Applicant Information

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part A: Applicant Information[2]

Part A should include information regarding the applicant for the submission. An applicant may be a manufacturer or importer that submits an SE Report to receive 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 *

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 *

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

City *

State *

Zip Code *

_____-____

Point of Contact for Organization

First Name *

Middle Initial

Last Name *

Generational Suffix

Other

Generational Suffix, if Other

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

Location	Phone or Fax	Type
US	Phone	Mobile

Phone or fax number: (555) 555-5555

Ext:

+ Add Phone/Fax

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part A: Applicant Information[2]

Part A should include information regarding the applicant for the submission. An applicant may be a manufacturer or importer that submits an SE Report to receive 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 *

Middle Initial

Last Name *

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

Country *

Street Address Line 1 *

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

City *

Province/Territory *

Postal Code *

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - Amendment Information

You are in the **Amendment Information** section. This section requests information regarding the purpose of the amendment and the details of the content being amended, and includes the following parts:

Part A: Amendment Purpose
Part B: Update to Product Properties (if applicable)
Part C: Cross-Referenced Information
Part D: Related Submissions
Part E: Referenced Tobacco Product Master File(s) (TPMF) (optional)
Part F: Amendment Contents
Part G: Certification Statement

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - Amendment Information

Part A: Amendment Purpose

Use Part A to provide the purpose for this amendment. Information provided in Part A will determine which additional parts need to be completed.

SE(s) Being Amended

List the FDA Submission Tracking Number (STN) and Product Identifier (PD) Number, or STN.PD# (e.g., SE5679840.PD1), assigned to the application being amended

Subject(s) of the Amendment

Select the subject(s) of the amendment (select all that apply):

- [ ] **Response to Deficiency Letter**
- [ ] **Response to Environmental Information Request Letter**
- [ ] **Response to Information Request Letter**
- [ ] **Request for Extension of Time to Respond to Deficiency Letter**
- [x] **Request to Withdraw the SE Report**

Provide the name and STN.PD# of product(s) being withdrawn *

- [ ] Select to indicate that the withdrawal is due to a health or safety concern related to the tobacco product

- [ ] **Update to Unique Identification Information**
  - If selected, you must provide FDA Form 3965b for any amended product properties with this submission and add STN.PD# in Addtional Properties

- [x] **Update to Product Properties**
  - If selected, provide updates in Section II Part C

- [x] **Change in Cross-Referenced Information**
  - If selected, provide updates in Section II Part D

- [x] **Change in Related Submissions**
  - If selected, provide updates in Section II Part E

- [x] **Change in Tobacco Product Master File (TPMF) Referenced**
  - [ ] Letter of Authorization (LOA)
  - If selected, provide updates in Section II Part F

- [x] **Change in Submission Contents**

Provide summary of the change in submission contents

- [x] **Submit Adverse Experience Report**

Provide summary of the Adverse Experience Report

- [x] **Other**

Provide summary of the other subject(s) for this amendment not included above

Section II - Amendment Information

Part B: Predicate Product Evidence

Use this section only if the predicate has not been previously reviewed by FDA. To add evidence of commercial marketing, use the *Add Evidence of Commercial Marketing* button below to add a row to the table to capture the evidence. Use the *Add Evidence of Commercial Marketing* button to add additional rows to the table, as needed.

Evidence of Commercial Marketing

Evidence of Commercial Marketing as of Feburary 15, 2007

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)

Commercially Marketed Business Address

Country

Street Address Line 1

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

City

Province/Territory

Postal Code

+ Add Evidence of Commercial Marketing

To add a statement of affirmation, use the *Add Statement of Affirmation* button below to add a row to the table to capture the statement. Use the *Add Statement of Affirmation* button to add additional rows to the table, as needed.

Certification Statement Regarding Availability of Health Information

Statement of Affirmation

Name of Responsible Official

john doe

Name of Predicate Tobacco Product(s)

Predicate 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, 5:57:25 pm

+ Add Statement of Affirmation

Section II - Amendment Information

Part C: Update to Product Properties (if applicable)

Part C is required as you selected "Update Product Properties" in Section II Part A as a subject of the amendment. For the addition, update, or removal of any new product's properties, use the *Add Update to New Product Properties* button below to add a row to the table to capture the change to the product's properties. Within the table, utilize a single row for each update, and use the *Add Update to New Product Properties* button to add additional rows to the table, as needed.

For the addition, update, or removal of any predicate product's properties, use the *Add Update to Predicate Product Properties* button below to add a row to the table to capture the change to the product's properties. Within the table, utilize a single row for each update, and use the *Add Update to Predicate Product Properties* button to add additional rows to the table, as needed.

Note: This section is not for submitting changes to Unique Identification Information. If there are no planned updates to product properties for this amendment, please update Section II Part A and unselect "Update to Product Properties."

Update to New Product Properties

New Product Name

STN.PD#

Action

Property Name

Previously Submitted Target Value

New/Updated Target Value

+ Add Update to New Product Properties

Update to Predicate Product Properties

Predicate Product Name

STN.PD#

Action

Property Name

Previously Submitted Target Value

New/Updated Target Value

+ Add Update to Predicate Product Properties

Section II - Amendment Information

Part D: Cross-Referenced Information

Part D is required as you selected "Change in Cross-Referenced Information" in Section II Part A as a subject of the amendment. For the addition, update, or removal of any cross-referenced information, use the *Add Change to Cross-Referenced Information* button below to add a row to the table to capture the change to the cross-referenced information. Within the table, utilize a single row for each change, and use the *Add Change to Cross-Referenced Information* button to add additional rows to the table, as needed.

Note: If there are no planned changes to cross-referenced information for this amendment, please update Section II Part A and unselect "Change in Cross-Referenced Information."

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

Cross-Referenced STN * _____

Action

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 Change to Cross-Referenced Information

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - Amendment Information

Part E: Related Submissions

Part E is required as you selected "Change in Related Submissions" in Section II Part A as a subject of the amendment. For the addition, update, or removal of a related submission, use the *Add Change to Related Submissions* button below to add a row to the table to capture the change to the related submission. Within the table, utilize a single row for each update, and use the *Add Change to Related Submissions* button to add additional rows to the table, as needed.

Note: If there are no planned changes in related submissions for this amendment, please update Section II Part A and unselect "Change in Related Submissions."

Related Submission(s) STN *

Action

Is the content relevant to all products within this submission?

- (●) Yes
- ( ) No

Information and sections to be referenced

+ Add Change to Related Submissions

BACK SAVE & EXIT NEXT

Section II - Amendment Information

Part F: Referenced Tobacco Product Master File(s) (TPMF) (optional)

Part F is required as you selected "Change in Tobacco Product Master File Referenced" in Section II Part A as a subject of the amendment. For the addition, update, or removal of any referenced TPMFs, use the *Add Change to Referenced TPMF* button below to add a row to the table to capture the change to the TPMF. Within the table, utilize a single row for each change, and use the *Add Change to Referenced TPMF* button to add additional rows to the table, as needed.

Note: If there are no planned changes to referenced TPMFs for this amendment, please update Section II Part A and unselect "Change in Tobacco Product Master File Referenced."

TPMF Owner

TPMF STN (assigned by FDA)

_____

Action

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 Change to Referenced TPMF

Expand All Sections

Section II - Amendment Information

Part G: Amendment Contents

Complete Part G to describe the items included in this amendment. For each item, provide a description of the content and indicate the file name/location of the content. To add Amendment Content, use the *Add Amendment Content* button below to add a row to the table to capture the information. Within the table, utilize a single row for each item, and use the *Add Amendment Content* button to add additional rows to the table, as needed.

Description *

Location

+ Add Amendment Content

Section II - Amendment Information

Part H: Certification Statement

The following certification statement is required for all SE Report Amendment Submissions. 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 an authorized representative of the applicant.

- For *Name of Responsible Official*, select or provide the name of the authorized representative(s) or U.S. agent who is signing the certification.
- For *Name of Applicant*, the applicant identified in Section I Part A has been automatically populated.

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

Certification Statement for SE Amendment

Name of Responsible Official *

Other

Other *

John Doe

Name of Applicant

Test Org A

I, **John Doe**, on behalf of **Test Org A**, hereby certify that **Test Org A** 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: John Doe	Digitally Signed On: October 7th 2024, 6:02:37 pm

+ Add 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

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.

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BACK SUBMIT NEXT

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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

Home › Create new submission

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

TC | General Correspondence

Name and Description

Submission Name *

Submission Description *

Additional Comments

Create Cancel

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Forms Approved: OMB No. 0910-0673, 0910-0879
Expiration Date: XX/XX/20XX

Tobacco General Correspondence (TC) Submission

Marketing a New Tobacco Product without a Marketing Granted Order (MGO) is illegal and may be subject to enforcement.[1]
Please carefully read the instructions below before completing this form.

Tobacco General Correspondence (TC)

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 tobacco-related general correspondence (TC) is any submission sent by any party that is not an application or intended to meet statutory requirements with the exception ofexcept for health summary and post market reports. A TC can include, but is not limited to:

- Formal Meeting Requests
- Changes in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact
- Requests for Change in Ownership
- Requests to Withdraw Previously Submitted General Correspondence

Complete the following question and answer form for the Tobacco General Correspondence (TC) Submission and when all required data has been entered click Submit to deliver the submission to the FDA's Center for Tobacco Products.

Instructions for Completion of the TC Amendment Form

Form FDA 3965a and FDA Form 4057a both contain the Tobacco General Correspondence (TC) Submission form, which is a required form for applicants submitting TC Submissions 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 Tobacco General Correspondence (TC) Submission.

This form is organized into the following sections:

- Applicant Identification
- General Correspondence Information
- 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 Numbers for this information collection are 0910-0673 and 0910-0879, and the expiration dates are XX/XX/20XX and XX/XX/20XX, respectively.

The burden time for this collection of information is estimated to average 10 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff

For PRA questions:
PRAStaff@fda.hhs.gov

Citations

The following citations are referenced throughout the form:

[1] A tobacco product that was introduced or delivered for introduction into interstate commerce after February 15, 2007, and prior to March 22, 2011, and for which a Substantial Equivalence (SE) Report was submitted by March 22, 2011, (Provisional SE Reports) may continue to be marketed unless FDA issues an order that the new product is not substantially equivalent.

[2] Required content and format as per §1107.18, §1114.7, §1114.15, and §1114.17.

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification[2]

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

Part A: Applicant Information

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part A: Applicant Information[2]

Part A should include information regarding the applicant for the submission. An applicant may be a manufacturer or importer that submits an SE Report to receive marketing authorization for a new tobacco product, or 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 *

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 *

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

City *

State *

Zip Code *

_____-____

Point of Contact for Organization

First Name *

Middle Initial

Last Name *

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

Location	Phone or Fax	Type	
Phone or fax number		Ext	

+ Add Phone/Fax

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section I - Applicant Identification

Part A: Applicant Information[2]

Part A should include information regarding the applicant for the submission. An applicant may be a manufacturer or importer that submits an SE Report to receive marketing authorization for a new tobacco product, or 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 *

Middle Initial

Last Name *

Generational Suffix

Professional Suffix

Position Title

Email Address

Phone or Fax Number(s)

+ Add Phone/Fax

Country *

Street Address Line 1 *

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

City *

Province/Territory *

Postal Code *

BACK SAVE & EXIT NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - General Correspondence Information

You are in the **General Correspondence Information** section. This section requests information regarding the subject(s) of the general correspondence, and includes the following parts:

Part A: Submission Information for General Correspondence
Part B: Add, Update, or Remove Applicant Information or Point of Contact (optional)
Part C: Request for Change in Ownership
Part D: Meeting Request

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - General Correspondence Information

Part A: Submission Information for General Correspondence

Use Part A to provide the subject(s) and summary for this correspondence. Information provided in Part A will determine which additional parts need to be completed.

Subject(s) of the Correspondence

Select the subject(s) of the correspondence (select all that apply):

Change in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact

- If selected, provide updates in Section II Part B

Request for Change in Ownership

- If selected, provide updates in Section II Part C

Meeting Request

- If selected, provide updates in Section II Part D

Request to Withdraw Previously Submitted General Correspondence

Provide summary of the request to withdraw a previously submitted General Correspondence *

Submit Adverse Experience Report

Provide summary of the Adverse Experience Report

Other

Provide summary of the other subject(s) for this amendment not included above

BACK | SAVE & EXIT | NEXT

Expand All Sections

Section II - General Correspondence Information

Part B: Add, Update, or Remove Applicant Information or Point of Contact (Optional)

Part B is required as you selected "Change in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact" in Section II Part A as a subject of the correspondence. For the addition, update, or removal of any Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact, use the *Add Change to Contact Information* button below to add a row to the table to capture the change to the contact. Within the table, utilize a single row for each update, and use the *Add Change to Contact Information* button to add additional rows to the table, as needed.

Note: If there are no planned changes to Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact for this correspondence, please update Section II Part A and unselect "Change in Authorized Representative, U.S. Agent, Manufacturer, or Point of Contact."

Panel

Change to Contact Information

Choose an Action: Update

Select the type of contact

Provide a brief description of the update here

Is this change applicable for all current FDA submissions?

Yes | No

Effective Date of Change

Current Contact Information on Record	Added/Updated Contact Information
First Name	First Name
Middle Initial	Middle Initial
Last Name	Last Name
Generational Suffix	Generational Suffix
Professional Suffix	Professional Suffix
Position Title	Position Title
Email Address	Email Address
Phone or Fax Number(s)	Phone or Fax Number(s)
+ Add Phone/Fax	+ Add Phone/Fax
Organization Name	Organization Name
Organization FDA-Assigned Facility Establishment Identifier (FEI) Number	Organization FDA-Assigned Facility Establishment Identifier (FEI) Number
Organization D&B DUNS® Number	Organization D&B DUNS® Number
Country	Country
Street Address Line 1	Street Address Line 1
Street Address Line 2 (Apt., Suite, Bldg., #)	Street Address Line 2 (Apt., Suite, Bldg., #)
City	City
Province/Territory	Province/Territory
Postal Code	Postal Code

+ Add Change to Contact Information

BACK | SAVE & EXIT | NEXT

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - General Correspondence Information

Part C: Request for Change in Ownership

Part C is required as you selected "Request for Change in Ownership" in Section II Part A as a subject of the correspondence. Use the *Add Application, Submission, and Product to be Transferred* button below to add a row to the table to capture the required information. Within the table, utilize a single row for each update, and use the *Add Application, Submission, and Product to be Transferred* button to add additional rows to the table, as needed.

A change in or transfer of ownership is for applicants (companies) who make a request to the FDA to transfer the rights and responsibilities for their applications and submissions to another company. The former applicant is the party that is listed in FDA's records to date. The new applicant is the party taking responsibility for the submissions. The new and former applicant must sign and submit certain information and statements to complete the transfer. This information is submitted as a general correspondence for all applications/submissions and not as an amendment to each application. The former applicant and new applicant must submit all information as outlined in Section III, Part B as applicable to their role in the transfer.

Note: The former applicant may select checkboxes for former and new if they are submitting all requirements on behalf of both parties. The new applicant cannot submit on behalf of the former. FDA will only process the request for change in ownership upon receipt of the request from the former applicant.

For change in ownership requests that include Premarket Tobacco Product Applications (PMTA) or Substantial Equivalence (SE) Reports, Form FDA 4057a and/or Form FDA 3965a are required. A single form can be provided for transfer requests that include multiple submission types. Changes in ownership that do not include SE or PMTA submissions do not require Form FDA 4057a or Form FDA 3965a, though we encourage the use of forms. The forms are available on the FDA website at: https://www.fda.gov/about-fda/reports-manuals-forms/forms.

The following are submission types that FDA will transfer:

- Marketing Applications
  - 910 Premarket Tobacco Application (PMTA)
  - 905(j)(1) Substantial Equivalence Reports (SE)
  - 905(j)(3) Exemption from Substantial Equivalence (EX)
  - 911 Modified Risk Tobacco Product Application (MRTPA)
- Submissions
  - 910(g) Investigational Tobacco Use (IU)
  - General Correspondence and Meeting Requests (TC)
  - Master Files (MF)
  - Grandfather Determination Requests (GF)
  - Pre-Existing Tobacco Products (PX)
  - Warning Plans (WP)
  - Other Media Notifications (OM)

Note: If there are no planned change in ownership requests for this correspondence, please update Section II Part A and unselect "Request for Change in Ownership."

Applications, Submissions, and Product Names to be Transferred

STN	PD Number (if applicable)	Product Name (if applicable)	

+ Add Application, Submission, and Product to be Transferred

Effective Date of Change

Enter the Effective Date of Change (mm/dd/yyyy)

Transfer Request Contents

This transfer request contains the following items (select all that apply):

A signed transfer of ownership request letter from the former applicant must include:

- The specific applications, submissions, and product names by STN being transferred.
- A statement that all rights of the applications have been transferred to the new applicant.
- Contact information for the new applicant (name, mailing address, phone number, and email).

A signed letter from the new applicant accepting the change in ownership from the former applicant must include:

- The specific applications, submissions, and product names by STN being accepted.
- A statement committing to all agreements, promises, and conditions made by the current applicant of record contained in the applications and submissions.
- A statement that the new applicant has a complete copy of the applications and submissions, or state they will request a copy per 21 CFR 20.40
- A statement that no modifications have been made to the transferred tobacco applications and submissions.
- Contact information for the new applicant (name, mailing address, phone number, and email).

BACK SAVE & EXIT NEXT

Expand All Sections

Section II - General Correspondence Information

Part D: Meeting Request

Part D is required as you selected "Meeting Request" in Section II Part A as a subject of the amendment. This is a request for a formal meeting which may include topics such as study design, earlier versions of the product, etc. Provide the requested information below and use the *Add Product to be Discussed at Meeting* button below to add a row to the table to capture the requested information about the product to be discussed at the meeting. Within the table, utilize a single row for each change, and use the *Add Product to be Discussed at Meeting* button to add additional rows to the table, as needed.

Note: If there are no planned meeting requests for this correspondence, please update Section II Part A and unselect "Meeting Request."

Meeting Request Information

Meeting Topic

Meeting Purpose

Meeting Format

Is the meeting information package included?

Yes No

Products to be Discussed at Meeting

Product Name	Product Use	Product Category (if applicable)	STN.PD# (if applicable)	
	Choose an item	Choose a product category		

+Add Product to be Discussed at Meeting

Meeting Request Contents

This meeting request contains the following items (select all that apply):

- **A preliminary list of the specific objectives/outcomes expected from the meeting.**
- **A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item.**
- **A preliminary list of specific critical questions, grouped by discipline (e.g., chemistry, clinical, non-clinical).**
- **A list of all individuals who will attend the meeting on your behalf, including titles and responsibilities.**

BACK SAVE & EXIT NEXT

Overview

Section I - Applicant Identification

Section II - General Correspondence Information

Submission Files

Review and Submit

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

BACK SUBMIT NEXT

Expand All Sections

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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