U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Welcome to the CTP Portal NextGen

Enter your existing CTP Portal username and password to log in.

Login

*Username:

Enter Username

Forgot Username?

*Password:

Enter Password

Forgot Password?

Terms of Use

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, including usage of personal devices and email systems 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.

☐ I Agree

Log In

What is the CTP Portal NextGen?

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.

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.

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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 Submissions

Package ID	Submission Name	Submission Type	Date Submitted
PKG0023145	Meeting Request for New Product D	TC - Meeting Request	12/01/2023
PKG0023114	SE for New Product C	SE - 905(j)(1)(A)(i) Substantial Equivalence	05/18/2023
PKG0023028	SE for New Product B	SE - 905(j)(1)(A)(i) Substantial Equivalence	05/17/2023
PKG0022945	PM for New Product A	PMTA - PreMarket Tobacco Application	04/12/2023
PKG0022762	Amendment for PM0024019	PMTA - PreMarket Tobacco Application Amendment	03/25/2023

Displaying 5 most recent View All

Recent Published Submissions

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SE0044966	PKG0023114	SE - 905(j)(1)(A)(i) Substantial Equivalence	05/18/2023
SE0043394	PKG0023028	SE - 905(j)(1)(A)(i) Substantial Equivalence	05/17/2023
PM0024019	PKG0022945	PMTA - PreMarket Tobacco Application	04/12/2023
PM0022778	PKG0022762	PMTA - PreMarket Tobacco Application Amendment	03/25/2023
TC0000083	PKG0023145	TC - Meeting Request	12/01/2023

Displaying 5 most recent View All

Click here to create a new submission.

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PKG0022945	PM for New Product A	PMTA - PreMarket Tobacco Application	04/12/2023
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PM0022778	PKG0022762	PMTA - PreMarket Tobacco Application Amendment	03/25/2023
TC0000083	PKG0023145	TC - Meeting Request	12/01/2023

Displaying 5 most recent View All

Select Submission Type

	Name	FDA Form ID	Version	Version Date	Last Create Date	Last Submit Date
○	Tobacco Substantial Equivalence Report Submission	3965	1.0	12/31/2024		
○	Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission	3965A	1.0	12/31/2024		
○	Premarket Tobacco Product Application (PMTA) Submission	4057	1.0	12/31/2024		
○	Premarket Tobacco Product Application (PMTA) Amendment and General Correspondence Submission	4057A	1.0	12/31/2024		

Cancel Next

Enter Submission Name and Description

Submission Name

Description

Premarket Tobacco Product Application (PMTA) Submission

Family Smoking Prevention and Tobacco Control Act

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).

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).

Premarket Tobacco Product Applications

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

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

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

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

*Red asterisks indicate required fields.

Paperwork Reduction Act

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB Control Number for this information collection is 0910-0879 and expiration date xx/xx/xxxx. The time required to complete this information collection is estimated to average 10 - 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.

Applicant Identification

Applicant Information:

Is the applicant an organization or an individual?

- ○ Organization
- ○ Individual

Applicant Identification

Look up Contact
Copy Contact
Clear Data

Organization Information:

Organization Name

Other Organization Names (if applicable)

Organization Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number

Organization Headquarters' D&B DUNS® Number

Submit Date

mm/dd/yyyy

Country

State, Province, or Territory

Street Address Line 1

Street Address Line 2

Apt., Suite, Bldg., #

City

ZIP or Postal Code

Point of Contact for Organization:

First Name

Middle Initial

Last Name

Generational Suffix

Professional Suffix

Position Title

Phone Number

Fax Number

Email Address

Applicant Identification

Look up Contact
Copy Contact
Clear Data

Individual Information:

First Name

Middle Initial

Last Name

Submit Date

mm/dd/yyyy

Generational Suffix

Professional Suffix

Position Title

Country

State, Province, or Territory

Street Address Line 1

Street Address Line 2

Apt., Suite, Bldg., #

City

ZIP or Postal Code

Phone Number

Fax Number

Email Address

Applicant Identification

Authorized Representative or U.S. Agent Information:

☐ Select if authorized representative or U.S. agent is the same as the applicant identified

Identify the authorized representative OR a U.S. agent.

○ Authorized representative
○ U.S. agent

Contact Information for the Authorized Representative or U.S. Agent:

First Name

Middle Initial

Last Name

Generational Suffix

Professional Suffix

Position Title

Organization Name

Country

State, Province, or Territory

Street Address Line 1

Street Address Line 2

Apt., Suite, Bldg., #

City

ZIP or Postal Code

Phone Number

Fax Number

Email Address

Applicant Identification

Alternate Point of Contact Information (Optional):

First Name	Last Name	Alternate Role	Organization Name	
John	Doe	Applicant	Company Co	
Jane	Doe	Authorized representative	Company Co	

Add Another

Applicant Identification

Alternate Point of Contact Information (Optional):

First Name	Last Name	Alternate Role	Organization Name	
John	Doe	Applicant	Company Co	
Jane	Doe	Authorized representative	Company Co	

Select alternate

First Name | Middle Initial | Last Name

Generational Suffix | Professional Suffix

Position Title

Organization Name

Country | State, Province, or Territory

Street Address Line 1

Street Address Line 2

City

ZIP or Postal Code

Phone Number

Fax Number

Email Address

Cancel Save

Add Another

Applicant Identification

Manufacturer Information:

☐ Select if manufacturer is the same as the applicant identified

Organization Name

Organization Headquarters' FDA-assigned
FEI Number (if applicable)

Organization Headquarters' D&B
DUNS® Number (if applicable)

☐ Select here if manufacturer address is the same as applicant address provided

Country

State, Province, or Territory

Street Address Line 1

Street Address Line 2

Apt., Suite, Bldg., #

City

ZIP or Postal Code

Point of Contact for Manufacturer:

First Name

Middle Initial

Last Name

Generational Suffix

Professional Suffix

Position Title

Phone Number

Fax Number

Email Address

Applicant Identification

Manufacturer/Packaging/Sterilization Sites Information:

Organization Name	POC First Name	POC Last Name	Type of Site	
Company Co	John	Doe	Manufacturer	
Company Co	Jane	Doe	Repacker/Relabeler	

Add Another

Applicant Identification

Manufacturer/Packaging/Sterilization Sites Information:

Organization Name	POC First Name	POC Last Name	Type of Site	
Company Co	John	Doe	Manufacturer	
Company Co	Jane	Doe	Repacker/Relabeler	

Select type of site

Organization Name

Organization Headquarters' FDA-assigned FEI Number (if applicable)

Organization Headquarters' D&B DUNS® Number (if applicable)

Division Name (if applicable)

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

○ Yes ○ No

Country | State, Province, or Territory

Street Address Line 1

Street Address Line 2

City

ZIP or Postal Code

Point of Contact Information for Manufacturing/Packaging/Sterilization Sites

First Name | Middle Initial | Last Name

Generational Suffix | Professional Suffix

Position Title

Phone Number

Fax Number

Email Address

Cancel | Save

Add Another

New Tobacco Product Information

Use required Form FDA 4057b – Premarket Tobacco Product Application Grouping Product Submission Spreadsheet to provide new product information. The form is available on the FDA website.

Upload Form

Previous Exit Save Next

General Submission Information

Submission Type *

Identify submission type (select one)

- ○ Standard PMTA
- ○ Resubmission
- ○ Supplemental

Products Previously Commercially Marketed in the United States

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

Product Name	Marketing Date
	mm/dd/yyyy

Add Another

Cross-Reference Information (Optional)

Cross-Reference Information

Complete Part B if the application includes one or more cross-reference(s) to another PMTA or MRTPA 21 CFR § 1114.7(b), § 1114.15(b), or § 1114.17(b). Supplemental PMTAs and resubmissions may cross-reference content in standard PMTAs. Standard PMTAs should not cross-reference another Standard PMTA or other pending applications with the exception of a pending MRTPA for the same tobacco product. Add additional Cross-Reference Information, as needed.

Cross-Reference STN

Is the content relevant to all products within this submission?

- ○ Yes
- ○ No

List all applicable product name(s)

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

Add Another

Referenced Tobacco Product Master File(s) (TPMF) (Optional)

Referenced Tobacco Product Master File(s) (TPMF)

Complete Part C if the application includes a Tobacco Product Master File (TPMF) 21 CFR § 1114.7 (b)(2). Add additional TPMFs, as needed.

TPMF Owner

TPMF STN (assigned by FDA)

Is the content applicable to all products within this submission?

- ○ Yes
- ○ No

List all applicable product name(s)

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

Right of reference included?

- ○ Yes
- ○ No

Add Another

Formal Meetings Held With FDA Pertaining to the New Product(s) (Optional)

Formal Meetings held with FDA pertaining to the New Product(s)

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. Add additional meetings, as needed.

Submission STN

Meeting Held Date

mm/dd/yyyy

Is the meeting relevant to all products within this submission?

- Yes
- No

List all applicable product name(s)

Add Another

Application Contents

This application contains the following items. Select all that apply and indicate file name and location of application content.

Administrative Content:

- [ ] Cover Letter
  Location
- [ ] Comprehensive Index and Table of Contents
  Location:
- [ ] English Translations for Non-English Information
  Location:
- [ ] Request for FDA to refer PMTA to TPSAC
  Location:

Labeling and Marketing Plans:

- [ ] Specimens of all Proposed Labelling
  Location
- [ ] Description of Marketing Plans
  Location:

Inspections:

- [ ] Location and Contact Information for Each Location Subject to Potential Inspection
  Location

Scientific Content:

- [ ] General Information
  Location
- [ ] Descriptive Information
  Location:
- [ ] Product Samples
  Location:
- [ ] Statement of Compliance with 21 CFR part 25
  Location:
- [ ] Summary
  Location:
- [ ] Product Formulation
  Location:
- [ ] Manufacturing
  Location:
- [ ] Literature Search
  Location:
- [ ] Organized References
  Location:
- [ ] Health Risk Investigations
  Location:
- [ ] Study Reports
  Location:

Statements of Compliance With Federal Food, Drug, and Cosmetic (FD&C) Act

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

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

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and

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

Certification Statements

Applications must contain the following certifications, as appropriate for the specific type of PMTA, with the appropriate information inserted, as described in each parenthetical, signed by an authorized representative of the applicant:

I. Certification Statement for Standard PMTAs
ii. Modified Tobacco Product Certification for Supplemental PMTAs
iii. Same Product Certification for Resubmissions
iv. Different Product Certification for Resubmissions
v. Financial Interest and Arrangements of Clinical Investigators Certification Statement

---

For the following section, insert the name of the authorized representative as identified in Section I Part B or Part C, the name of the organization being represented as identified in Section I Part A, the individual new tobacco product(s), and the name of the previously submitted PMTA product(s). Complete the information for all applications. If you choose to print and wet sign the certification statements, upload them as a separate document from 4057 to maintain the dynamic fields in Adobe and ensure all content is available for FDA to process, read, review, and archive.

Certification Statement for Standard PMTAs:

Name of Responsible Official: *

Applicant Name: *

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

Signature

Sign above

Date:

mm/dd/yyyy

Modified Tobacco Product Certification for Supplemental PMTAs

Name of Responsible Official *

Applicant Name: *

Tobacco Product Name: *

Product Modifications: *

Previously Submitted Tobacco Products: *

STN of Previously Submitted PMTA(s): *

I, **[Name of Responsible Official]**, on behalf of the applicant **[Applicant Name]**, certify that **[New Tobacco Product Name]** has a different **[Describe each modification to the product]** than **[Name of Previously Submitted Tobacco Product(s))]** described in **[STN of previously submitted PMTA]**. I certify that **[New Tobacco Product Name]** understands this means there is no other modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product. I also certify that **[Name of Applicant]** will maintain all records that substantiate the accuracy of this application, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

Signature

Sign above

Date:

mm/dd/yyyy

Same Tobacco Product Certification for Resubmission

Name of Responsible Official *

Applicant Name: *

New Tobacco Product Name: *

STN of Previously Submitted PMTA(s): *

I, **[Name of Responsible Official]**, on behalf of **[Name of Applicant]**, certify that this submission for **[New Tobacco Product Name]** responds to all deficiencies outlined in the marketing denial order issued in response to *(STN of the previously submitted PMTA)* and the new tobacco product described herein is identical to the product described in the previously submitted PMTA. I certify that **[Name of Applicant]** understand this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature. I also certify that **[Name of Applicant]** will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct. and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

Signature

Sign above

Date:

mm/dd/yyyy

Different Tobacco Product Certification for Resubmission

Name of Responsible Official *

Applicant Name: *

New Tobacco Product Name: *

STN of Previously Submitted PMTA(s): *

Product Modifications: *

Original Tobacco Product: *

I, [**Name of Responsible Official**], on behalf of the applicant, [**Name of Applicant**] certify that this submission for [**New Tobacco Product Name**] responds to all deficiencies outlined in the marketing denial order issued in response to [**STN of the Previously Submitted PMTA**] and the new tobacco product described herein has a different [**Product Modifications**] than [**Name of Original Tobacco Product**] described in [**STN of the Previously Submitted PMTA**] but its otherwise identical to [**Name of Original Tobacco Product**] described in [**STN of the Previously Submitted PMTA**] I certify that [**Name of Applicant**] understands this mans there is no modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product, except for the [**Product Modifications**] I also certify that [**Name of Applicant**] will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in an matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

Signature

Sign above

Date:

mm/dd/yyyy

Financial Interest and Arrangements of Clinical Investigators Certification Statement

Name of Responsible Official *

Company Name: *

I, **[Name of Responsible Official]**, on behalf of **[Company Name]**, certify that there are no financial conflicts of interest or have included documentation fully disclosing any potential financial conflicts of interest required by 21 CFR § 1114.7(k)(3)(ii).

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

Signature

Sign above

Date:

mm/dd/yyyy

Review and Submit Submission to CTP

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.

At this time, you may save and exit this submission to return to it at a later time. To do so, simply click Save and then click Exit. To re-open this submission after exiting, navigate to the Submissions > View All Unsubmitted Submissions page, click the actions button next to this submission in the table and select Edit.

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.

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.

Submission Received

Your submission has been delivered to the Center for Tobacco Products (CTP) for additional processing. Please refer to the Submissions table at any time to view the status of your submission. Once CTP processes the submission, CTP will notify your organization that the submission is available to view in the CTP Portal NextGen.

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

Exit View Submissions Create New Submission