DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

REGISTRATION OF TOBACCO PRODUCT ESTABLISHMENTS AND LISTING OF TOBACCO PRODUCTS IN COMMERCIAL DISTRIBUTION

Form Approved: OMB No. 0910-0650
Expiration Date: xx/xx/20xx

The registration of tobacco product manufacturing establishments and/or the listing of tobacco products, either through electronic submission via FDA's Tobacco Registration and Product Listing Module Next Generation (TRLM-NG) system, or through mailed submission if FDA has granted a waiver from electronic submission, ***does not denote FDA authorization*** *for the marketing of tobacco products in the United States (U.S.). FDA does not consider new tobacco products to be authorized for the legal sale and distribution in the U.S. unless they have an* ***FDA marketing authorization order in effect****,* ***regardless of whether those products are properly listed.*** **Marketing a new tobacco product without an FDA marketing authorization order in effect is illegal and may be subject to enforcement. Please consult appendices in Section XII for terminology, statutory requirements, and additional resources.**

TABLE OF CONTENTS

NOTICE

Please **type or legibly write your responses** to all questions.
An item followed by an asterisk **(*)** denotes a **required** field.

Submissions will be considered **incomplete** if required information is not provided.

Unless FDA has granted a waiver, official correspondents (i.e., the owner, operator, or their authorized representative) must submit establishment registration and product list information online using FDA's free TRLM-NG module. To create a TRLM-NG industry account, please visit: https://trlm-ng-industry.fda.gov/login.

This system greatly streamlines the data entry process for establishment registration and product listing and facilitates efficient (and timely) submissions to FDA and efficient processing, review, and archiving of the submission once at FDA. TRLM-NG provides an interactive template form to report establishment registration and product listing data and an automatic acknowledgement of FDA receipt. It also allows official correspondents to attach and track large numbers of material files for labeling, advertising, and consumer information submissions.

FDA strongly encourages review of the Form FDA 3741 navigation guide and completion of the submission checklist in Section II of this form. Incomplete submissions may experience delays in processing or require FDA correspondence to obtain missing information.

If an official correspondent is unable to submit establishment registration and product lists online using TRLM-NG, they may request a waiver from electronic submission. To request a waiver, Registrants must send a letter to FDA's Document Control Center (DCC), at the address below. If FDA grants the waiver, Form FDA 3741 and Form FDA 3741b can be printed and mailed or saved to a USB flash drive or DVD, along with any material files, and mailed to DCC. Please note, if additional space is required for any section or part, please print out additional pages of the applicable section or part and attach them to the form package.

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SECTION I – SUBMISSION TYPE

Instructions for Section I – Submission Type

Section I identifies the submission type. Options include an initial submission of the form or an update to a previously submitted form.

Submission Type

1. Indicate submission type *(select one)**:

☐ **Initial Establishment Registration and Product List and Material File Submission**
(per sections 905(c) and 905(i)(1) of the Food, Drug, and Cosmetic Act (FD&C Act)) (Intended for initial registration and product list submissions)

☐ **Update Only to Previously Submitted Establishment Registration Submission**
(per section 905(b) of the FD&C Act) (Intended for submitters who have previously submitted a registration, but need to make updates to the establishment information)

☐ **Update Only to Previously Submitted Product List and/or Material File Submission**
(per section 905(i)(3) of the FD&C Act) (Intended for submitters who have previously submitted a product list but need to make updates to the product list and/or associated material files)

☐ **Update to Both Previously Submitted Establishment Registration and Previously Submitted Product List and/or Material File Submission** *(per sections 905(b) and 905(i)(3) of the FD&C Act) (Intended for submitters who need to update the establishment information and the product list and/or associated material files)*

☐ **Confirmation That Neither Previously Submitted Establishment Registration Nor Previously Submitted Product List and/or Material File Submission information Has Changed Since Last Submission**
(Intended for submitters to confirm no changes to report)
If this box is checked, complete the rest of this section then skip to Section XI – Certification Statement.

Identification of Registration to Update (if update to previous submission)

2. Provide the TRLM-NG Registration ID number (RG ID #) that FDA previously assigned*: RG _____
(Leave blank if this is an initial establishment registration and product list submission)

Submission Method

3. Confirm whether the submission will be submitted electronically through TRLM-NG or mailed to DCC as a paper or mixed media submission.*

☐ Electronically through TRLM-NG *(proceed to Section II – Form FDA 3741 Navigation Guide and Submission Checklist).*

☐ By mail, printouts, USB/DVD to be sent to DCC *(provide proof of waiver from electronic submission below).*

Note: All tobacco product establishment registration and product listing information must be submitted electronically through TRLM-NG, unless a waiver from electronic submission has been requested and granted by FDA. FDA must have proof of a valid waiver to be able to accept mailed submissions.

4. Waiver Request Submission Date (*mm/dd/yyyy)*	5. Waiver STN*

6. Waiver Status*	7. Date Notified of Waiver Request Status *(mm/dd/yyyy)*
☐ Waiver Granted ☐ Waiver Denied ☐ Other *(Specify)* _____	

SECTION II – FORM FDA 3741 NAVIGATION GUIDE AND SUBMISSION CHECKLIST

Instructions for Section II – Form FDA 3741 Navigation Guide and Submission Checklist

The Form FDA 3741 Navigation Guide provides a section-by-section breakdown of the content of this form and shows all required sections and parts as applicable depending on submission type. After reviewing the Form Navigation Guide, please fill out and complete the Submission Checklist.

Part A – Form FDA 3741 Navigation Guide

Instructions for Part A – Form FDA 3741 Navigation Guide

Please review the Form Navigation Guide. This Navigation Guide is intended to provide the submitter with an overview of which sections (marked with an "X") need to be filled out depending on submission type.

Form FDA 3741 Section Content	Initial Establishment Registration and Tobacco Product List and Material File Submission	Update **Only** to Previously Submitted Establishment Registration Submission	Update **Only** to Previously Submitted Tobacco Product List and/or Material File Submission	Update to **both** a Previously Submitted Establishment Registration **and** Previously Submitted Tobacco Product List and/or Material File Submission	Confirmation That **Neither** Previously Submitted Establishment Registration **Nor** Previously Submitted Tobacco Product List and/or Material File Submission Information Has Changed Since Last Submission
Section I - Submission Type	X	X	X	X	X
Section II - Form FDA 3741 Navigation Guide and Submission Checklist	(optional)	(optional)	(optional)	(optional)	
Section III - Registration Information for Initial Submission	X				
Section IV - Establishment Information for Initial Submission	X				
Section V - Tobacco Product List Information for Initial Submission	X				
Section VI - Labeling, Advertising, Consumer Information (Material File(s)) for Initial Submission	X				
Section VII - Updates to Registration Information		X (if applicable)		X (if applicable)	
Section VIII - Updates to Establishment Information		X (if applicable)		X (if applicable)	
Section IX - Updates to Tobacco Product List Information			X (if applicable)	X (if applicable)	
Section X - Updates to Labeling, Advertising, Consumer Information (Material File(s))			X (if applicable)	X (if applicable)	
Section XI - Certification Statement	X	X	X	X	X

Part B – Submission Checklist

Instructions for Part B – Submission Checklist

Please fill out the table below (as demonstrated in the Form Navigation Guide) to indicate the content you intend to provide or update for this form.

Form FDA 3741 Section Content	Initial Establishment Registration and Tobacco Product List and Material File Submission	Update **Only** to Previously Submitted Establishment Registration Submission	Update **Only** to Previously Submitted Tobacco Product List and/or Material File Submission	Update to **both** a Previously Submitted Establishment Registration **and** Previously Submitted Tobacco Product List and/or Material File Submission	Confirmation That **Neither** Previously Submitted Establishment Registration **Nor** Previously Submitted Tobacco Product List and/or Material File Submission Information Has Changed Since Last Submission
Section I - Submission Type					
Section II - Form FDA 3741 Navigation Guide and Submission Checklist					
Section III - Registration Information for Initial Submission					
Section IV - Establishment Information for Initial Submission					
Section V - Tobacco Product List Information for Initial Submission					
Section VI - Labeling, Advertising, Consumer Information (Material File(s)) for Initial Submission					
Section VII - Updates to Registration Information					
Section VIII - Updates to Establishment Information					
Section IX - Updates to Tobacco Product List Information					
Section X - Updates to Labeling, Advertising, Consumer Information (Material File(s))					
Section XI - Certification Statement					

SECTION III – REGISTRATION INFORMATION FOR INITIAL SUBMISSION

Instructions for Section III – Registration Information for Initial Submission

Section III includes identifying the official correspondent (e.g., person registering a tobacco product manufacturing facility and submitting a product list for that establishment's commercially distributed tobacco products).

Part A – Official Correspondent Information for Initial Submission

Instructions for Part A – Official Correspondent Information for Initial Submission

The official correspondent is the owner, operator, or their authorized representative seeking to register an establishment that engages in the manufacture, preparation, compounding, or processing of tobacco products. Per Section 905(a)(1) of the FD&C Act, the term "manufacture, preparation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or end user. Examples of manufacturing include assembling, processing, homogenizing, mixing, formulating, labeling, or packaging. Manufacturers include specification developers, third-party manufacturers, bulk tobacco product manufacturers, and repackagers/relabelers.

The official correspondent is considered the primary TRLM-NG user and shall serve as FDA's primary official correspondent for all information contained within the establishment registration, tobacco product list, and associated labeling, advertising, and consumer information (material files). The official correspondent shall serve as the TRLM-NG account manager and ensure all establishment registration, product list, and associated labeling, advertising, consumer information (material file) information is current and accurate in the TRLM-NG database. The official correspondent may add additional TRLM-NG secondary users to the registration (see Section III.B – TRLM-NG Secondary User Information for Initial Submission) to assist with reviewing and updating establishment registration and tobacco product list information.

Official Correspondent Information

1. First Name*	2. Middle Initial	3. Last Name*

4. Generational Suffix	5. Professional Suffix	6. Position Title*

7. Business Name*	8. Fax Number

9. Phone Number *(select one and provide number)**	10. Email Address*
☐ Work ☐ Mobile	☐ Select if Waiver

Official Correspondent for the Registration

11. Who is the official correspondent for the establishment(s) being registered in this registration? *(select all that apply)**

☐ **Establishment Owner**
Has an ownership interest in one or more tobacco product establishments being registered.

☐ **Establishment Operator**
Has management authority for one or more tobacco product establishments being registered.

☐ **Authorized Representative of Owner**
Responsible official authorized to represent the owner of a tobacco product establishment being registered.

☐ **Authorized Representative of Operator**
Responsible official authorized to represent the operator of a tobacco product establishment being registered.

Part B – TRLM-NG Secondary User Information for Initial Submission

Instructions for Part B – TRLM-NG Secondary User Information for Initial Submission

The TRLM-NG secondary user(s) is/are authorized by the official correspondent as additional individuals who will need access to review and/or update the registration and product list. In instances where the official correspondent is nonresponsive, FDA may contact the TRLM-NG secondary user for CTP registration and listing issues. If more than one TRLM-NG secondary user needs to be added, submit additional sections for each additional user as needed.

Note: *TRLM-NG secondary users can be added to the registration at any time after the initial submission as needed. There is no requirement for official correspondents to add TRLM-NG secondary users. If responding "no" to #1, the remainder of Section III, Part B can be left blank.*

1. Will additional individuals (other than the official correspondent) need access to review and update the registration in TRLM-NG?

☐ Yes *(continue below to provide requested information on secondary user(s))*

☐ No *(proceed to Section IV.A – Establishment Information for Initial Submission)*

TRLM-NG Secondary User Information

2. First Name		3. Middle Initial	4. Last Name
5. Generational Suffix	6. Professional Suffix	7. Position Title	
8. Business Name		9. Fax Number	
10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile		11. Email Address ☐ Select if Waiver	

TRLM-NG Secondary User's Association to Registered Establishment(s)

12. What is the TRLM-NG Secondary User's association to the establishment(s) being registered in this registration? *(select all that apply)*

☐ **Establishment Owner**
Has an ownership interest in one or more tobacco manufacturing establishments being registered.

☐ **Establishment Operator**
Has management authority for one or more tobacco manufacturing establishments being registered.

☐ **Authorized Representative of Owner**
Responsible official authorized to represent the owner of a tobacco product establishment being registered.

☐ **Authorized Representative of Operator**
Responsible official authorized to represent the operator of a tobacco product establishment being registered.

13. Specify level of access the TRLM-NG secondary user will need for this registration (*select one)*:

☐ **Read only:** Can only view registration materials, but cannot make changes, certify, or submit establishment registration and product list information.

☐ **Review and edit:** Has full access, can fill in for primary TRLM-NG account manager and edit, certify, and submit establishment registration and product list information.

SECTION IV – ESTABLISHMENT INFORMATION FOR INITIAL SUBMISSION

Instructions for Section IV – Establishment Information for Initial Submission

Complete Section IV to identify the tobacco product establishment(s) required to be registered and provide key information on their operations and contact information. Please complete all parts of Section IV for each establishment that engages in the manufacture, preparation, compounding, or processing of tobacco products. Use additional copies of this section for each additional establishment.

Part A – Establishment Information for Initial Submission

A.1 – Establishment Identification

1. Establishment Legal Name*	2. Does the establishment do business by any other name?* ☐ Yes *(continue to IV.A.1 #3)* ☐ No *(skip to IV.A.1 #4)*	3. Establishment DBA Name(s) *(if applicable)*

4. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Establishment D&B DUNS® Number *(if applicable)*

Establishment Physical Address

6. Street Address Line 1*		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section IV.A.2 – Establishment Details

Establishment Mailing Address

13. Street Address Line 1*		14. Street Address Line 2 *(Apartment, Suite, Building Number)*	
15. City*	16. State, Province, or Territory*	17. Country*	18. ZIP or Postal Code*

A.2 – Establishment Details

1. Provide the establishment's website address(es) that concern tobacco products.*

2. Establishment Corporate Affiliations

Identify any corporate affiliations, (i.e., parent, subsidiary, or other affiliate companies) if applicable. If the establishment is not part of a larger corporate structure, this section may be left blank.

Parent Company Legal Name	Parent Company Physical Address
Subsidiary Company Legal Name	Subsidiary Company Physical Address
Affiliate Company Legal Name	Affiliate Company Physical Address

3. Is the establishment located in a personal residence?	4. Is English the primary language spoken at the establishment?
☐ Yes ☐ No	☐ Yes ☐ No, specify primary language spoken: _____

5. Is the establishment located on Indian Country?*

☐ Located on Indian Country – provide name of Tribe: _____

☐ Not located on Indian Country *(Continue below to Section IV.A.3 – Establishment Operations)*

A.3 – Establishment Operations

1. Date *(mm/dd/yyyy)* establishment began manufacturing tobacco products for commercial distribution in the U.S.*

***Note**: specification development is included in manufacturing activities subject to FD&C section 905*

2. Establishment Location *(select one)**	3. Tobacco Product Type(s) Associated With Establishment *(select all that apply)**	4. Commercial Distribution Destination of Establishment's Products
☐ Domestic Establishment ☐ Foreign Establishment	☐ Finished Tobacco Products ☐ Consumer Use Bulk Tobacco Products ☐ For Further Manufacturing (FFM)	☐ Domestic Market *(U.S.)* ☐ Foreign Market *(For Export From U.S.)*

5. Indicate which activities are performed at the registered establishment *(select all that apply)**

General Tobacco Product Manufacturing Activities

☐ Assembling
☐ Compounding
☐ E-Liquid filling/packaging (bottling or pod filling)
☐ E-Liquid production (mixing/blending nicotine, flavorings, PG/VG, or other ingredients)
☐ Formulating
☐ Homogenizing
☐ Labeling
☐ Mixing
☐ Packaging
☐ Preparing
☐ Processing
☐ Relabeling
☐ Repackaging
☐ Specification development for tobacco products
☐ Third-party manufacturing of tobacco products

6. Indicate additional operations performed at the registered establishment *(select all that apply)*

Additional Operations

☐ Distributing Tobacco Products *(specify types of tobacco products distributed)*

☐ Cigarettes
☐ Cigars
☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
☐ Heated Tobacco Products (HTP)
☐ Pipe Tobacco Products
☐ Roll-Your-Own Tobacco Products (RYO)
☐ Smokeless Tobacco Products
☐ Waterpipe Tobacco Products (Hookah)
☐ Oral Nicotine Products
☐ Other Tobacco Products *(Specify)* _____

☐ Importing Tobacco Products *(specify types of tobacco products imported)*

☐ Cigarettes
☐ Cigars
☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
☐ Heated Tobacco Products (HTP)
☐ Pipe Tobacco Products
☐ Roll-Your-Own Tobacco Products (RYO)
☐ Smokeless Tobacco Products
☐ Waterpipe Tobacco Products (Hookah)
☐ Oral Nicotine Products
☐ Other Tobacco Products *(Specify)* _____

☐ Retailing Tobacco Products *(specify types of tobacco products sold)*

- ☐ Cigarettes
- ☐ Cigars
- ☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
- ☐ Heated Tobacco Products (HTP)
- ☐ Pipe Tobacco Products
- ☐ Roll-Your-Own Tobacco Products (RYO)
- ☐ Smokeless Tobacco Products
- ☐ Waterpipe Tobacco Products (Hookah)
- ☐ Oral Nicotine Products
- ☐ Other Tobacco Products *(Specify)*

☐ ENDS Coil or Device Repairs

☐ Storing Tobacco Products

☐ Testing Tobacco Products

☐ Exporting Tobacco Products

☐ Advertising

☐ Other *(Specify)*

A.4 – Establishment Contact Information

Instructions for Part A.4 – Establishment Contact Information

Provide contact information for the establishment to be registered. Use additional copies of this section for each additional establishment being registered.

Establishment Contact Information

1. Establishment Point of Contact: *(select all that apply)*

☐ **Is the same as the official correspondent information provided in Section III, Part A**
(Provide the first and last name and then proceed to Tribe Contact Information (if applicable) or Section IV.B – Establishment Owner Information)

☐ **Is the same as the TRLM-NG secondary user information provided in Section III, Part B**
(Provide the first and last name and then proceed to Tribe Contact Information (if applicable) or Section IV.B – Establishment Owner Information)

☐ **Has not been introduced in previous sections** *(Continue below to provide establishment contact information)*

2. First Name*	3. Middle Initial	4. Last Name*

5. Generational Suffix	6. Professional Suffix	7. Position Title*

8. Business Name*	9. Fax Number

10. Phone Number *(select one and provide number)** ☐ Work ☐ Mobile	11. Email Address* ☐ Select if Waiver

Tribe Contact Information *(if establishment affiliated with Tribe)*

12. First Name	13. Middle Initial	14. Last Name

15. Generational Suffix	16. Professional Suffix	17. Position Title

18. Tribe Name	19. Fax Number
20. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	21. Email Address ☐ Select if Waiver

Part B – Establishment Owner Information for Initial Submission

Instructions for Part B – Establishment Owner Information for Initial Submission

Provide details on the owner of the establishment being registered.

B.1 – Owner's Business Identification

1. Owner's Business Legal Name*	2. Does the owner's business go by any other name?* ☐ Yes *(continue to IV.B.1 #3)* ☐ No *(skip to IV.B.1 #4)*	3. Owner's Business DBA Name(s) *(if applicable)*
4. Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*	

Owner's Business Physical Address

6. Street Address Line 1*		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section IV.B.2 – Owner's Business Structure.

Owner's Business Mailing Address

13. Street Address Line 1*		14. Street Address Line 2 *(Apartment, Suite, Building Number)*	
15. City*	16. State, Province, or Territory*	17. Country*	18. ZIP or Postal Code*

B.2 – Owner's Business Structure

1. Select the type of business structure most applicable to the owner's business *(select one)**

☐ **Sole Proprietorship** *(provide information for the individual owner)*
☐ **Partnership** *(provide information on each partner)*
☐ **Corporation**, **Including Limited Liability** *(provide information on each corporate officer and director)*

2. Provide the indicated information for each key official within the owner's business structure*

Corporate Officer and/or Company Official #1

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #2			
First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #3			
First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #4			
First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #5			
First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #6			
First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Location of Formation of Legal Business Entity

3. Identify the state, territory, or possession of formation *(if in the U.S.)* or the country of incorporation *(if outside the U.S.)**

B.3 – Owner's Contact Information

Instructions for Part B.3 – Owner's Contact Information

Provide contact information for the owner of the establishment to be registered (if not previously provided).

1. Owner's contact information: *(select all that apply)**

☐ **Is the same as the official correspondent information provided in Section III, Part A**
(Provide the first and last name and then proceed to Section IV.C – Establishment Operator Information for Initial Submission)

☐ **Is the same as the TRLM-NG secondary user information provided in Section III. Part B**
(Provide the first and last name and then proceed to Section IV.C –Establishment Operator Information for Initial Submission)

☐ **Is the same as the establishment contact information provided in Section IV, Part A**
(Provide the first and last name and then proceed to Section IV.C –Establishment Operator Information for Initial Submission)

☐ **Has not been introduced in previous sections** *(Continue below to provide owner's contact information)*

2. First Name*		3. Middle Initial	4. Last Name*
5. Generational Suffix	6. Professional Suffix	7. Position Title*	
8. Business Name*		9. Fax Number	
10. Phone Number *(select one and provide number)** ☐ Work ☐ Mobile		11. Email Address* ☐ Select if Waiver	

Part C – Establishment Operator Information for Initial Submission

Instructions for Part C – Establishment Operator Information for Initial Submission

Provide details on the operator of the establishment being registered.

☐ Select if establishment owner is also the operator. *(Proceed to Section IV.D – Brand Owner Information for Initial Submission. Otherwise, continue below.)*

C.1 – Operator's Business Identification

1. Operator's Business Legal Name*	2. Does the operator's business go by any other name?* ☐ Yes *(continue to IV.C.1 #3)* ☐ No *(skip to IV.C.1 #4)*	3. Operator's Business DBA Name(s) *(if applicable)*
4. Operator's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*		5. Operator's Business Headquarters' D&B DUNS® Number *(if applicable)*

Operator's Business Physical Address

6. Street Address Line 1*		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section IV.C.2 – Operator's Business Structure.

Operator's Business Mailing Address

13. Street Address Line 1*		14. Street Address Line 2 *(Apartment, Suite, Building Number)*	
15. City*	16. State, Province, or Territory*	17. Country*	18. ZIP or Postal Code*

C.2 – Operator's Business Structure

1. Select the type of business structure most applicable to the operator's business *(select one)**

☐ **Sole Proprietorship** *(provide information for the individual owner of the operator's business)*

☐ **Partnership** *(provide information on each partner)*

☐ **Corporation**, **Including Limited Liability** *(enter information on each corporate officer and director)*

2. Provide the indicated information for each key official within the operator's business structure*

Corporate Officer and/or Company Official #1

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #2

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #3

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #4

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #5

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #6

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Location of Formation of Legal Business Entity

3. Identify the state, territory, or possession of formation *(if in the U.S.)* or the country of incorporation *(if outside the U.S.)**

Instructions for Part C.3 – Operator's Contact Information

Provide contact information for the operator of the establishment to be registered (if not previously provided).

1. Operator's contact information: *(select all that apply)**

☐ **Is the same as the official correspondent information provided in Section III, Part A**
(Provide the first and last name and then proceed to Section IV.D – Brand Owner Information for Initial Submission)

☐ **Is the same as the TRLM-NG secondary user information provided in Section III, Part B**
(Provide the first and last name and then proceed to Section IV.D – Brand Owner Information for Initial Submission)

☐ **Is the same as the establishment contact information provided in Section IV, Part A**
(Provide the first and last name and then proceed to Section IV.D – Brand Owner Information for Initial Submission)

☐ **Is the same as the owner contact information provided in Section IV, Part B**
(Provide the first and last name and then proceed to Section IV.D – Brand Owner Information for Initial Submission)

☐ **Has not been introduced in previous sections** *(Continue below to provide operator's contact information)*

2. First Name*		3. Middle Initial	4. Last Name*
5. Generational Suffix	6. Professional Suffix	7. Position Title*	
8. Business Name*		9. Fax Number	
10. Phone Number *(select one and provide number)** ☐ Work ☐ Mobile		11. Email Address* ☐ Select if Waiver	

Part D – Brand Owner Information for Initial Submission

Instructions for Part D – Brand Owner Information for Initial Submission

You may use the fields below to provide details on who owns a brand, through creation, acquisition, trademark, patent, copyright, or otherwise, and has directly or through license, the control and/or direction of the brand(s) manufactured at the establishment being registered. For each product brand associated with the establishment, provide the requested brand owner information below. You may submit additional sections for each additional brand owner.

Note: *While the below fields in this Part are not required to complete registration, completing this Part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding brand owner information.*

D.1 – Establishment Brand Owner Identification

1. Does the establishment being registered own all, some, or none of the product brands manufactured at the establishment? *(i.e., is the registered establishment also the product brand owner) (select one)*

☐ **Has ownership over all product brands**
Establishment to be registered is also the product brand owner for all products manufactured.
(proceed to Section IV.E – Direct Account(s) for Initial Submission)

☐ **Has ownership over some product brands**
Establishment to be registered owns some, not all, of the product brands manufactured.
(continue below)

☐ **Has ownership over none of the product brands**
Establishment to be registered has no ownership of any of the product brands manufactured.
(skip to IV.D.1 #3)

2. Which product brands manufactured at the establishment does the establishment being registered have brand ownership of?

3. Which product brands manufactured at the establishment does the establishment being registered **not** have brand ownership of? *(provide brand owner information)*

D.2 – Brand Owner's Business Identification		
1. Brand Owner's Business Legal Name	2. Does the brand owner's business go by any other name? ☐ Yes *(continue to IV.B.1 #3)* ☐ No *(skip to IV.B.1 #4)*	3. Brand Owner's Business DBA Name(s) *(if applicable)*
4. Brand Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Brand Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*	

6. What brands are owned by this brand owner as they pertain to products manufactured at this establishment?

Brand Owner's Business Physical Address			
7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section IV.D.3 – Brand Owner's Contact Information.

Brand Owner's Business Mailing Address			
14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

D.3 – Brand Owner's Contact Information			
1. First Name		2. Middle Initial	3. Last Name
4. Generational Suffix	5. Professional Suffix	6. Position Title	
7. Business Name		8. Fax Number	
9. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile		10. Email Address ☐ Select if Waiver	

Part E – Direct Account(s) for Initial Submission

Instructions for Part E – Direct Account(s) for Initial Submission

You may use the fields below to provide details on the registered establishment's direct account(s). Examples of direct account(s) for registered finished product manufacturing establishments include retailers, distributors, and wholesalers. An example of a direct account for bulk tobacco product manufacturing establishments would be the finished product manufacturer that receives the bulk tobacco products for further manufacturing into a finished tobacco product. An example of a direct account for product specification developing establishments would be the manufacturing establishment that further manufactures the products to the specifications developed. You may submit additional sections for each additional direct account.

Note: *While the below fields in this Part are not required to complete registration, completing this Part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding direct account information*

E.1 – Direct Account Reporting Status

1. Does the establishment being registered in Section IV, Part A have any Direct Account(s) to report? *(select one)*

☐ Yes *(continue below)*
☐ No *(Proceed to Section IV.F – Establishment Importer(s) and Consignee(s) Information for Initial Submission)*

E.2 – Direct Account Business Information

1. Direct Account is *(select one)*

☐ Retailer
☐ Distributor
☐ Wholesaler
☐ Finished Product Manufacturer *(if registered establishment was bulk tobacco product manufacturer)*
☐ Other *(Specify)*

2. Direct Account's Business Legal Name	3. Does the direct account's business go by any other name? ☐ Yes *(continue to IV.E.2 #4)* ☐ No *(skip to IV.E.2 #5)*	4. Direct Account's Business DBA Name(s) *(if applicable)*

5. Direct Account's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Direct Account's D&B DUNS® Number *(if applicable)*

Direct Account's Physical Address

7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section IV.E.3 – Direct Account's Contact Information.

Direct Account's Mailing Address

14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

E.3 – Direct Account's Contact Information

Instructions for Part E.3 – Direct Account's Contact Information

Provide contact information for the direct account.

1. First Name	2. Middle Initial	3. Last Name

4. Generational Suffix	5. Professional Suffix	6. Position Title

7. Business Name	8. Fax Number

9. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	10. Email Address ☐ Select if Waiver

Part F – Establishment Importer(s) and Consignee(s) Information for Initial Submission

Instructions for Part F – Establishment Importer(s) and Consignee(s) Information for Initial Submission

You may use the fields below to provide details on the importer of record and the designated party to receive imported products (i.e. consignee) as applicable. You may submit additional sections for each additional importer or consignee.

Note: *While the below fields in this Part are not required to complete registration, completing this Part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding importer and consignee information.*

F.1 – Importer/Consignee Reporting Status

1. Does the establishment being registered in Section IV, Part A have any importers and/or consignees to report?

☐ Yes *(continue below to indicate who imports the listed tobacco products into the U.S. for sale or distribution and/or who is named on the bill of lading)*

☐ No *(proceed to Section V – Tobacco Product List Information for Initial Submission)*

F.2 – Importer/Consignee Business Information

1. Business and contact information indicated below are for establishment's *(select one)*

☐ Importer

☐ Consignee

☐ Both *(registered establishment's importer is also the consignee)*

2. Importer/Consignee's Business Legal Name	3. Does the importer/consignee's business go by any other name? ☐ Yes *(continue to IV.F.2 #4)* ☐ No *(skip to IV.F.2 #5)*	4. Importer/Consignee's Business DBA Name(s) *(if applicable)*

5. Importer/Consignee's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Importer/Consignee's D&B DUNS® Number *(if applicable)*

Importer/Consignee's Business Physical Address

7. Street Address Line 1	8. Street Address Line 2 *(Apartment, Suite, Building Number)*

9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section IV.F.3 – Importer/Consignee's Contact Information.

Importer/Consignee's Business Mailing Address			
14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

F.3 – Importer/Consignee's Contact Information

1. Contact information before is for: *(select one)*

☐ Importer ☐ Consignee ☐ Both

2. First Name	3. Middle Initial	4. Last Name
5. Generational Suffix	6. Professional Suffix	7. Position Title
8. Business Name		9. Fax Number
10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile		11. Email Address ☐ Select if Waiver

SECTION V – TOBACCO PRODUCT LIST INFORMATION FOR INITIAL SUBMISSION

Instructions for Section V – Tobacco Product List Information for Initial Submission

Provide the requested tobacco product list information for every tobacco product manufactured at each establishment being registered with FDA. Please clearly indicate which tobacco product(s) are associated with each establishment whose information was provided for in Section IV, Part A. Every tobacco product listed must have a universal product code (UPC), or alternative industry product identification number, as well as its unique identifying information, including, as applicable, product category and subcategory, package type, characterizing flavor (e.g., tobacco, menthol, flavored, unflavored), a way to quantify the product amount (i.e., by providing the numeric value and units for product quantity, product quantity mass, portion count, or portion mass, as applicable for the product subcategory), an indication of the nicotine source (i.e., tobacco derived nicotine, non-tobacco derived nicotine, both, none) and nicotine concentration (where applicable). Provide additional properties as needed to uniquely identify your product and distinguish it from other products within the same brand or product line if the property is not otherwise included in the options below. See Form FDA 3741b tobacco product list spreadsheet for required fields per product subcategory and selectable options per field for each product subcategory.

***Note**: You are required to submit your establishment registration and product list electronically unless a waiver from electronic submission has been granted to you by FDA*

- *If you are submitting electronically, you have two options to complete Section V: 1) you may complete Form FDA 3741b in lieu of Parts A and B.1 #13 and #14, upload Form FDA 3741b directly into TRLM-NG, and then return to this form (FDA 3741) to complete Parts B.1 #1-12, B.2 ,C, and D below; or 2) you may complete Section V of Form FDA 3741 for each product to be listed. Use additional sheets as needed for each additional product.*
- *If you are submitting by mail, you must use Form FDA 3741b to provide the information necessary to complete Section V, Parts A and B.1 #13 and #14. Following completion of Form FDA 3741b, you must use this form (FDA 3741) to complete Parts B.1 #1-12, B.2, C, and D below.*

Part A – Tobacco Product Identification

Instructions for Part A – Tobacco Product Identification

Use Form FDA 3741b to provide the unique product identifiers and attributes for each product. If you are submitting electronically, you may complete Part A for each product to be listed instead of Form FDA 3741b. Use additional sheets as needed for each additional product.

A.1 – Tobacco Product Identifiers

1. Product Name (including brand and subbrand)*

2. Does product have a Universal Product Code (UPC)? *(select one)**

☐ Yes, provide UPC: _____

☐ No, select if product does not have a UPC *(must provide an Alternative Industry Product Identification Number below)*

3. Alternative Industry Product Identification Number (if no UPC)	4. Alternative Industry Product Identification Number Type *(select one)*
	☐ SKU (Stock Keeping Unit) ☐ Catalog or Item # ☐ EAN (International Article Number) ☐ GTIN (Global Trade Item Number) ☐ Other *(Specify)*

5. Product Category and Subcategory*

☐ **Cigarettes**

- Filtered Cigarettes
- Non-Filtered Cigarettes
- Cigarettes – Other *(Specify)*

☐ **Cigars**

- Cigar Component
- Cigar Tobacco Filler
- Filtered, Sheet-Wrapped Cigars
- Unfiltered, Leaf-Wrapped Cigars
- Unfiltered, Sheet-Wrapped Cigars
- Cigars – Other *(Specify)*

☐ **Electronic Nicotine Delivery Systems (ENDS)/(Vapes)**

- Closed E-Cigarette
- Closed E-Liquid
- ENDS Component
- Open E-Cigarette
- Open E-Liquid
- ENDS – Other *(Specify)*

☐ **Oral Nicotine Products**

- Nicotine Pouch
- Oral Nicotine – Other *(Specify)*

☐ **Roll-Your-Own (RYO) Tobacco Products**

- RYO Filter
- RYO Filtered Cigarette Tube
- RYO Non-Filtered Cigarette Tube
- RYO Paper Tip
- RYO Tobacco Filler
- RYO Rolling Paper
- RYO – Other *(Specify)*

☐ **Smokeless Tobacco Products**

- Dissolvable
- Loose Chewing Tobacco
- Loose Dry Snuff
- Loose Moist Snuff
- Loose Snus
- Portioned Chewing Tobacco
- Portioned Moist Snuff
- Portioned Snus
- Smokeless – Other *(Specify)*

☐ **Heated Tobacco Products (HTP)**

- Closed HTP
- Open HTP
- HTP Consumable
- HTP Component
- HTP – Other *(Specify)*

☐ **Pipe Tobacco Products**

- Pipe
- Pipe Component
- Pipe Tobacco Filler
- Pipe – Other *(Specify)*

☐ **Waterpipe Tobacco Products**

- Waterpipe
- Waterpipe Component
- Waterpipe Heat Source
- Waterpipe Tobacco Filler
- Waterpipe – Other *(Specify)*

☐ **Other Products**

- Other Products – Other *(Specify)*

6. Tobacco Product Type *(select one)**

☐ Finished Tobacco Product ☐ Consumer Use Bulk Tobacco Product ☐ For Further Manufacturing (FFM)

A.2 – Product Attributes/Properties

1. Package Type*

Tobacco Product Quantity*
(at least one of the below must be provided to quantitate the product as appropriate per product category/subcategory)

2. Product Quantity *(Numeric value and units)*	3. Product Quantity Mass *(Numeric value and units)*
4. Portion Count *(Numeric value and units)*	5. Portion Mass *(Numeric value and units)*

Tobacco Product Flavor

6. Characterizing Flavor *(select one)**

☐ Menthol ☐ Tobacco ☐ Unflavored ☐ Flavored *(specify below)*

7. Flavor Name *(if flavored)*	8. Flavor Description *(if flavored)*

Tobacco Product Nicotine Attributes

9. Nicotine Concentration *(Numeric value)*	10. Nicotine Concentration *(Units) (select one)*
	☐ mg/ml ☐ %W/W ☐ mg/unit, *(specify)* _____ ☐ None

11. Nicotine Source *(select one)**

☐ Tobacco Derived Nicotine (TDN) ☐Non-Tobacco Derived Nicotine (NTN) ☐ Both ☐ None

E-Liquid Concentration (if applicable)		
12. PG *(Numeric value)*	13. VG *(Numeric value)*	14. E-Liquid Volume *(Numeric value and units)*

Device/Battery Information (if applicable)	
15. Wattage *(Numeric value and units)*	16. Battery Capacity *(Numeric value and units)*

Length (if applicable)

17. Length Description

☐ King ☐ Long ☐ XL ☐ Queen ☐ None ☐ Other: *(specify)* _____

18. Length *(Numeric value and units)*

Width (if applicable)

19. Width *(Numeric value and units)*

Diameter (if applicable)		
20. Diameter Description	21. Diameter Format	22. Diameter *(Numeric value and units)*

Height (if applicable)

23. Height *(Numeric value and units)*

Portion Thickness (if applicable)

24. Portion Thickness *(Numeric value and units)*

Other (if applicable)		
25. Tobacco Cut Style	26. Filter Ventilation *(Percentage)*	27. Number of Hoses
28. Source of Energy	29. Wrapper Material	
30. Tip Type	31. Additional Properties	

Part B – Tobacco Product – Establishment Associations and Manufacturing and Commercial Distribution Status

Instructions for Part B – Tobacco Product – Establishment Associations and Manufacturing and Commercial Distribution Status

For each product listed, indicate which registered establishment is responsible for manufacturing the product, when the product was first introduced for commercial distribution, and the commercial distribution destination of the product. Please note, while a product can be manufactured and distributed for both domestic and foreign distribution, due to differing requirements that product must appear as two separate line items on Form FDA 3741b based on the difference in commercial distribution destination.

B.1 – Associated Manufacturing Establishment Information and Manufacturing and Commercial Distribution Status

Instructions for Part B.1 – Associated Manufacturing Establishment Information and Manufacturing and Commercial Distribution Status

Submit additional sheets for each additional establishment that needs to be associated to the product identified above.

Note: *If more than one establishment is registered, the products listed can be uploaded to TRLM-NG using the Form FDA 3741b product list spreadsheet and then associated to all or specific establishments as needed. If certain registered establishments are only engaged in manufacturing activities for some of the listed products, you will need to specify which establishment(s) manufacturing activities are performed on the product listed. Multiple products can be selected through the TRLM-NG user interface to associate to an establishment on the registration. If only one establishment is on the registration, that establishment will be the default associated establishment for all listed products.*

Associated Establishment Identification

1. Establishment Legal Name*	2. Does the establishment do business by any other name?* ☐ Yes *(continue to V.B.1 #3)* ☐ No *(skip to V.B.1 #4)*	3. Establishment DBA Name(s) *(if applicable)*

4. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Establishment D&B DUNS® Number *(if applicable)*

Associated Establishment Physical Address

6. Street Address Line 1*	7. Street Address Line 2 *(Apartment, Suite, Building Number)*

8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

Manufacturing and Commercial Distribution Status

12. Date Tobacco Product Introduced for Commercial Distribution *(mm/dd/yyyy)**

13. Commercial Distribution Destination of Establishment's Products *(select one)** ☐ Domestic Market *(U.S.)* ☐ Foreign Market *(for Export From U.S.)*	14. Country of Origin *(select one)** ☐ Domestic Establishment *(U.S.)* ☐ Foreign Establishment

B.2 – Other Businesses (not required to register and list) that are associated with this product

1. Other Associated Business is: *(select one)*

☐ Brand Owner ☐ Importer ☐ Consignee ☐ Retailer ☐ Distributor ☐ Wholesaler

☐ Other *(Specify)* _____

Identification of the Other Associated Businesses (not required to register and list)		
2. Business Legal Name	3. Does business go by any other name? ☐ Yes *(continue to V.B.2 #4)* ☐ No *(skip to V.B.2 #5)*	4. Business DBA Name(s) *(if applicable)*
5. Business Website		

Associated Business Physical Address			
6. Street Address Line 1		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

Part C – Tobacco Product Standards and Information for Tobacco Products for Export

Instructions for Part C – Tobacco Product Standards and Information for Tobacco Products for Export

For each product listed, indicate if there are any applicable product standards under FD&C Act section 907 and identify the product standard. For each product for export (i.e., product with a country of origin in the U.S. and commercial distribution destination of "foreign export") please confirm whether or not the exported product conforms to applicable product standards per section 907 of the FD&C Act. Report the destination country and quantity of non-conforming tobacco products intended for exported to the indicated destination country. Section V.C #2-4 can be left blank for all products whose country of origin is the U.S. and commercial distribution destination is domestic.

Tobacco Product Standards and Information for Tobacco Products for Export

1. Is your tobacco product subject to any tobacco product standards under section 907 of the FD&C Act? *(select one)**

☐ Yes *(provide applicable tobacco product standards and continue below)*

☐ No *(provide reason tobacco product standards do not apply to this product and then proceed to Section V, Part D)*

Tobacco Products for Export

For domestic tobacco products intended for export that are subject to an applicable tobacco product standard (leave blank if commercial distribution destination is the U.S.).

2. Does your exported tobacco product conform to applicable tobacco product standards per section 907 of the FD&C Act? *(select one)**

☐ Yes *(proceed to Section V, Part D)*

☐ No *(continue below)*

3. Specify the manner in which the exported tobacco product does not conform to applicable tobacco product standards.*

4. Which destination country(ies) were these tobacco products exported to in the previous calendar year?*
(Provide the quantity of tobacco product shipped to each country of destination during the previous calendar year.)

Destination Country	Quantity of Non-Conforming Tobacco Product Exported

Part D – Tobacco Product Marketing Authorization Status and Information

Instructions for Part D – Tobacco Product Marketing Authorization Status and Information

In the sections below, please indicate whether the listed tobacco product has an associated STN for a premarket tobacco product application (PMTA), substantial equivalence (SE) report, exemption from substantial equivalence request (EX REQ), pre-existing (PX) product review, or modified risk tobacco product application (MRTPA). See FDA's website for additional information on marketing authorization pathways and pre-existing products: https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product.

Tobacco Product Marketing Authorization Status and Information

1. Tobacco product is *(select all that apply)**

- ☐ A new tobacco product (not commercially marketed in the U.S. as of February 15, 2007)
- ☐ A pre-existing tobacco product (commercially marketed in the U.S. as of February 15, 2007)
- ☐ A modified risk tobacco product
- ☐ A new tobacco product that is substantially equivalent to a predicate tobacco product that was commercially marketed in the U.S. as of February 15, 2007
- ☐ A provisional SE tobacco product marketed after February 15, 2007, but before March 11, 2011
- ☐ Has a SE exemption request

2. Date product was first marketed in the U.S. *(mm/dd/yyyy)*

3. Has a PMTA, MRTPA, SE report, or SE exemption request been submitted for the tobacco product being listed, or has the product been submitted for voluntary PX review? *(select one)**

- ☐ Yes *(continue below)*
- ☐ No *(proceed to Section VI)*

4. What marketing authorization pathways has the listed product been submitted for?
(select all that apply and provide associated STNs and date of submission)

☐ PMTA

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., PM0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ MRTPA

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., MR0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ SE Report

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., SE0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ SE exemption request (EX REQ)

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., EX0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ Voluntary pre-existing tobacco product review

Associated STNs *(provide accompanying PD #s, if applicable) (e.g., PX0000000)**	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

5. Current marketing authorization status of product *(select all that apply)*

☐ Marketing Granted Order (MGO)
☐ Marketing Denial Order (MDO)
☐ Modified Risk Order
☐ Modified Risk Denial Order
☐ Substantial Equivalence Order (SE Order)
☐ Not Substantially Equivalent Order (NSE Order)
☐ SE Exempt Order
☐ SE Not Exempt Order
☐ Pre-Existing Tobacco Product Status Determination
☐ Unable to Determine Pre-Existing Tobacco Product
☐ Other *(Specify)*

6. Submitter Name	7. Applicant Name
8. Product Name as Appeared on Submission	9. Date Notified of Most Recent Status by FDA *(mm/dd/yyyy)*
10. Predicate Tobacco Product *(if applicable)*	11. Modification *(if applicable)*

12. Modified Risk Statement(s) and Representation(s) *(if applicable)*

SECTION VI – LABELING, ADVERTISING, CONSUMER INFORMATION (MATERIAL FILE(S)) FOR INITIAL SUBMISSION

Instructions for Section VI – Labeling, Advertising, Consumer Information (Material File(s)) for Initial Submission

Use the fields below to provide the requested information on labeling, advertising, and consumer information (material file(s)) associated with the listed tobacco products. Files must be uploaded electronically via TRLM-NG. Files can only be mailed as a hard copy or USB/DVD to DCC if a valid waiver for electronic submission has been requested and approved by FDA. Please clearly indicate which tobacco product(s) are associated with each material file submission.

All tobacco products must have specific labeling documentation on file with FDA as part of the establishment registration and product listing process. Tobacco products for which a tobacco product standard has been established under FD&C Act section 907 (21 USC 387g), or which is subject to FD&C Act section 910 (21 USC 387e), must have an exact, legible, full color copy of all product labeling. For any other tobacco product, all product labeling, copies of all consumer information, and a representative sampling of advertisements must be submitted. Official correspondents will be unable to submit their establishment registration and tobacco product list without a copy of all labeling for each tobacco product.

Provide material file information for each individual labeling, consumer information, and advertising material file being submitted, as appropriate, for the tobacco products listed in Section V – Tobacco Product List Information for Initial Submission. Submit additional copies of this part for each additional material file being submitted.

When submitting a labeling material file for such products in Section VII, the label for the domestic distributed product must be in English and clearly indicate it is intended for sale in the U.S. The foreign distributed product label should be in the language of the commercial distribution destination country with an accompanying English translation that clearly indicates what country it is intended for sale in.

***Note:** While some of the below fields in this Part are not required to complete product listing, completing this part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding labeling, consumer information, and advertising, (material file) information for the products listed.*

Part A – Labeling, Advertising, Consumer Information (Material File) Identification

1. Material File Name*	2. Date First Disseminated *(mm/dd/yyyy)**

3. Material Contains *(select all that apply)**

☐ Labeling ☐ Advertising ☐ Consumer Information

***Note:** The submitter's designation of the material being submitted as labeling, advertising, or consumer information does not necessarily reflect FDA's interpretation or designation.*

4. Select the type of labeling/advertising/consumer information from the options below that best describes the type of material *(select all that apply)*

☐ Affixed Tag	☐ Email	☐ Pamphlet	☐ Social Media
☐ Brochure	☐ Flyer or Handout	☐ Point of Sale	☐ Text Messaging
☐ Business Card	☐ Instructions	☐ Press Release	☐ Trade Show Material
☐ Carton	☐ Large Sign	☐ Package Label	☐ Website or Banner
☐ Catalog	☐ Magazine, Periodical, or Print	☐ Reviews or Feedback	☐ Wrapper
☐ Cautions or Warnings	☐ Mobile App	☐ Rewards or Loyalty Cards	☐ Other *(Specify)*
☐ Cigar Box	☐ Outer Container	☐ Shipping and Packaging	
☐ Coupons	☐ Package Inserts	☐ Small Sign	
☐ Digital Information	☐ Package Onserts		
☐ Direct Mailer			

5. Official Product Website Address(es) or URL(s)

6. Location of Label on Finished Product Packaging *(select one)*

☐ Top ☐ Front ☐ Side ☐ Back ☐ Bottom ☐ Other *(Specify)*

7. Will there be a submission of a package label plan?

☐ Yes ☐ No

8. What variables are captured in the product variation index?

9. Additional Material File Properties *(if applicable)*

Part B – Tobacco Product – Labeling, Advertising, Consumer Information (Material File) Associations

1. Tobacco Product Name (including brand and subbrand)*	2. Universal Product Code (UPC)*

3. Alternative Industry Product Identification Number (if no UPC)	4. Alternative Industry Product Identification Number Type *(select one)* ☐ SKU (Stock Keeping Unit) ☐ Catalog or Item # ☐ EAN (International Article Number) ☐ GTIN (Global Trade Item Number) ☐ Other *(Specify)*

5. Tobacco Product Category	6. Tobacco Product Subcategory

SECTION VII – UPDATES TO REGISTRATION INFORMATION

Part A – Updates to Official Correspondent Information

Instructions for Part A – Updates to Official Correspondent Information

Please note, all references to the "official correspondent" in this part are specifically referring to their role as the TRLM-NG account manager. Complete this section if the original official correspondent is no longer affiliated with the registration, and the previous TRLM-NG account manager role in the system needs to be transferred to a new official correspondent to resume updating the registration.

1. Have there been any changes to the official correspondent/TRLM-NG account manager or their corresponding information (see Section III.A) since the last submission? *(select one)**

☐ Yes *(provide the effective date of change and continue below to provide the updated information)*

☐ No *(proceed to Section VII.B – Updates to TRLM-NG Secondary User Information)*

Effective Date of Change *(mm/dd/yyyy)* _____

2. Select the nature of the update *(select one)**

☐ **Updating information for existing official correspondent**
(Complete Section VII.A.1 – Updates to Official Correspondent Information and proceed to Section VII.B – Updates to Existing TRLM-NG Secondary User Information)

☐ **Transferring official correspondent role to another individual (existing official correspondent will be removed from the registration)**
(Complete Section VII.A.2 – Transferring Official Correspondent Role for Registration and proceed to Section VII.B – Updates to TRLM-NG Secondary User Information)

☐ **Transferring official correspondent role to another individual but remaining as secondary user (existing official correspondent will become a secondary user)**
(If any of the existing official correspondent's information needs to be updated, provide the updated values in Section VII.A.1 – Updates to Official Correspondent Information and complete Section VII.A.2 – Transferring Official Correspondent Role for Registration and proceed to Section VII.B – Updates to TRLM-NG Secondary User Information)

Part A.1 – Updates to Official Correspondent Information

Instructions for Part A.1 – Updates to Official Correspondent Information

Provide the updated information for the fields that have changed since the last submission. Leave the field blank if there have been no updates to report since the last submission for that field.

Updates to Existing Official Correspondent Information

1. First Name		2. Middle Initial	3. Last Name
4. Generational Suffix	5. Professional Suffix	6. Position Title	
7. Business Name		8. Fax Number	
9. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile		10. Email Address ☐ Select if Waiver	

Updates to Existing Official Correspondent for the Registration

11. What is the existing official correspondent's association to the registered establishment(s) on this registration? *(select all that apply)*

☐ **Establishment Owner**
Has an ownership interest in one or more registered tobacco product establishments on this registration.

☐ **Establishment Operator**
Has management authority for one or more registered tobacco product establishments on this registration.

☐ **Authorized Representative of Owner**
Responsible official authorized to represent the owner of a registered tobacco product establishment on this registration.

☐ **Authorized Representative of Operator**
Responsible official authorized to represent the operator of a registered tobacco product establishment on this registration.

Part A.2 – Transferring Official Correspondent Role for Registration

Instructions for Part A.2 – Transferring Official Correspondent Role for Registration

Provide the requested information for the new official correspondent who will be serving as the official correspondent/TRLM-NG account manager.

Note: *When transferring the registration to a new official correspondent/TRLM-NG account manager, the former official correspondent's access to the registration will be revoked unless they specify that they would like to remain on the registration as a secondary user.*

New Official Correspondent Information

1. First Name*		2. Middle Initial	3. Last Name*
4. Generational Suffix	5. Professional Suffix	6. Position Title*	
7. Business Name*		8. Fax Number	
9. Phone Number *(select one and provide number)** ☐ Work ☐ Mobile		10. Email Address* ☐ Select if Waiver	

New Official Correspondent for the Registration

11. What is the new official correspondent's association to the registered establishment(s) on this registration? *(select all that apply)**

☐ **Establishment Owner**
Has an ownership interest in one or more registered tobacco product establishments on this registration.

☐ **Establishment Operator**
Has management authority for one or more registered tobacco product establishments on this registration.

☐ **Authorized Representative of Owner**
Responsible official authorized to represent the owner of a registered tobacco product establishment on this registration.

☐ **Authorized Representative of Operator**
Responsible official authorized to represent the operator of a registered tobacco product establishment on this registration.

Part B – Updates to TRLM-NG Secondary User Information

Instructions for Part B – Updates to TRLM-NG Secondary User Information

The TRLM-NG secondary user(s) is/are designated by the official correspondent as additional individuals who will need access to review and/or update the establishment registration and product list information. In instances where the official correspondent is non-responsive, FDA may contact the TRLM-NG secondary user for establishment registration and product listing issues. Complete this section if any of the previously submitted information for the TRLM-NG secondary user(s) has changed, if a TRLM-NG secondary user is no longer affiliated with the registered establishment, or if a new TRLM-NG secondary user needs to be added to the registration. Submit additional copies of this section as needed for each additional TRLM-NG secondary user added or whose information needs to be updated.

1. Have there been any changes to who is serving as the TRLM-NG secondary user or their corresponding information (see Section III, Part B) since the last submission? *(select one)**

☐ Yes *(provide the effective date of change and continue below to provide the updated information)*

☐ No *(proceed to Section VIII – Updates to Establishment Information)*

Effective Date of Change *(mm/dd/yyyy)* _____

2. Select the nature of the update *(select one)**

☐ **Updating information for or removing an existing TRLM-NG secondary user**
(Complete Section VII.B.1 – Updates to Existing TRLM-NG secondary user and proceed to Section VIII – Updates to Establishment Information)

☐ **Adding a new TRLM-NG secondary user to the registration**
(Skip to Section VII.B.2 – Adding a new TRLM-NG secondary user and proceed to Section VIII – Updates to Establishment Information)

Part B.1 – Updates to Existing TRLM-NG Secondary User's Contact Information

Instructions for Part B.1 – Updates to Existing TRLM-NG Secondary User's Contact Information

Indicate the TRLM-NG secondary user contact information that needs to be updated or if a current TRLM-NG secondary user needs to be removed from the registration. For changes to the TRLM-NG secondary user contact information, provide the updated information for the fields that have changed since the last submission. Leave the field blank if there have been no updates to report since the last submission for that field.

Identification of Existing TRLM-NG Secondary User to Update or Remove

1. First Name	2. Last Name	3. Email Address ☐ Select if Waiver

4. The existing TRLM-NG secondary user identified above needs to be *(select one)*

☐ Updated ☐ Removed
This will revoke access and remove the TRLM-NG secondary user indicated above *(proceed to Section VIII – Updates to Establishment Information)*

Updates to Existing TRLM-NG Secondary User's Contact Information

5. First Name	6. Middle Initial	7. Last Name

8. Generational Suffix	9. Professional Suffix	10. Position Title

11. Business Name	12. Fax Number

13. Phone Number *(select one and provide number)*	14. Email Address
☐ Work ☐ Mobile	☐ Select if Waiver

Updates to Existing TRLM-NG Secondary User's Association to Registered Establishment(s)

15. What is the existing TRLM-NG secondary user's association to the establishment(s) on this registration? *(select all that apply)*

☐ **Establishment Owner**
Has an ownership interest in one or more registered tobacco product establishments on this registration.

☐ **Establishment Operator**
Has management authority for one or more registered tobacco product establishments on this registration.

☐ **Authorized Representative of Owner**
Responsible official authorized to represent the owner of a registered tobacco product establishment on this registration.

☐ **Authorized Representative of Operator**
Responsible official authorized to represent the operator of a registered tobacco product establishment on this registration.

Updates to Existing TRLM-NG Secondary User Registration Access

16. Specify level of access the TRLM-NG secondary user will need for the registration (*select one)*:

☐ **Read only:** Can only view registration materials but cannot make changes, certify, or submit establishment registration and product list information.

☐ **Review and edit:** Has full access, can fill in for primary TRLM-NG account manager, and can edit, certify, and submit establishment registration and product list information.

Part B.2 – Adding a New TRLM-NG Secondary User

Instructions for Part B.2 – Adding a New TRLM-NG Secondary User
Provide the requested information for the new TRLM-NG secondary user to be added to the registration.

New TRLM-NG Secondary User's Contact Information

1. First Name	2. Middle Initial	3. Last Name

4. Generational Suffix	5. Professional Suffix	6. Position Title

7. Business Name	8. Fax Number

9. Phone Number *(select one and provide number)*	10. Email Address
☐ Work ☐ Mobile	☐ Select if Waiver

New TRLM-NG Secondary User's Association to Registered Establishment(s)

11. What is the TRLM-NG secondary user's association to the establishment(s) on this registration? *(select all that apply)*

☐ **Establishment Owner**
Has an ownership interest in one or more registered tobacco product establishments on this registration.

☐ **Establishment Operator**
Has management authority for one or more registered tobacco establishments on this registration.

☐ **Authorized Representative of Owner**
Responsible official authorized to represent the owner of a registered tobacco product establishment on this registration.

☐ **Authorized Representative of Operator**
Responsible official authorized to represent the operator of a registered tobacco product establishment on this registration.

12. Specify level of access the new TRLM-NG secondary user will need for this registration: (*select one)**

☐ **Read only:** Can only view registration materials, but cannot make changes, certify, or submit establishment registration and product list information.

☐ **Review and edit:** Has full access, can fill in for the primary TRLM-NG account manager to edit, certify, and submit establishment registration and product list information.

SECTION VIII – UPDATES TO ESTABLISHMENT INFORMATION

Instructions for Section VIII – Updates to Establishment Information

Confirm whether there have been any changes to the registered establishment's information since the last submission. If so, identify the establishment whose information needs to be updated and provide the updated values for the fields that changed. Submit additional copies of this section as needed for each additional establishment that needs to be updated or added.

Note: *At a minimum to identify the establishment that needs to be updated, provide the establishment name, FEI #, and physical address. If contact information for the establishment needs to be updated or removed, provide a name and email address. If a new establishment needs to be added to the registration, provide the same information required for initial establishment registration (per Section IV).*

Part A – Updates to Establishment Information

1. Have there been any changes to the establishment information for any of the registered establishments since the last submission? *(select one)**

☐ Yes *(provide the updated information on the establishment changes)*

☐ No *(skip to Section VIII.B – Updates to Owner Information)*

2. Select the appropriate summary of the change needed *(select all that apply)*:

☐ **Updating existing establishment information**
(Identify the existing establishment to be updated and provide updated values for fields that changed in VIII.A.1 – A.4)

☐ **Adding new establishment which recently began manufacturing**
(Complete VIII.A.1.1 – A.1.4 for the new establishment to be registered)

☐ **Inactivating an existing establishment that ceased manufacturing**
(Identify the existing establishment to be updated and provide the manufacturing status updates in VIII.A.5)

☐ **Re-activating an existing establishment that resumed manufacturing**
(Identify the existing establishment to be updated and provide the manufacturing status updates in VIII.A.5)

3. Effective Date of Change *(mm/dd/yyyy)** _____

Select applicable statement for the effective date of change provided above:

☐ New establishment was added, provided the date began manufacturing.

☐ Previously active establishment needs to be inactivated, provided the date the establishment ceased manufacturing.

☐ Previously inactive establishment needs to be reactivated, provided the date the establishment resumed manufacturing.

A.1 – Establishment Identification

Instructions for Part A.1 – Establishment Identification

Identify the establishment whose information has changed since last submission (Identification of Existing Establishment to Update) and then provide updated values for fields that changed (Updates to Establishment Information, Updates to Establishment Details, Updates to Establishment Operations). If a field did not change, leave it blank. Submit additional copies for each additional establishment that needs to be updated.

Identification of Existing Establishment to Update

1. Establishment Legal Name	2. Establishment DBA Name(s) *(if applicable)*
3. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	4. Establishment D&B DUNS® Number *(if applicable)*

Physical Address of Existing Establishment to Update

5. Street Address Line 1		6. Street Address Line 2 *(Apartment, Suite, Building Number)*	
7. City	8. State, Province, or Territory	9. Country	10. ZIP or Postal Code

Updates to Existing Establishment Information

11. Establishment Legal Name	12. Does the establishment do business by any other name? ☐ Yes *(continue to VIII.A.1 #13)* ☐ No *(skip to VIII.A.1 #14)*	13. Establishment DBA Name(s) *(if applicable)*
14. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*		15. Establishment D&B DUNS® Number *(if applicable)*

Updates to Existing Establishment Physical Address

16. Street Address Line 1		17. Street Address Line 2 *(Apartment, Suite, Building Number)*	
18. City	19. State, Province, or Territory	20. Country	21. ZIP or Postal Code

22. ☐ Select if mailing address is same as physical address. If the same, skip to Section VII.A.2 – Updates to Existing Establishment Details

Updates to Existing Establishment Mailing Address

23. Street Address Line 1		24. Street Address Line 2 *(Apartment, Suite, Building Number)*	
25. City	26. State, Province, or Territory	27. Country	28. ZIP or Postal Code

A.2 – Updates to Existing Establishment Details

Instructions for Part A.2 – Updates to Existing Establishment Details

For the identified establishment, provide updated values for fields that changed. If a field did not change, leave it blank. Submit additional copies for each additional establishment that needs to be updated.

1. Provide the establishment's website address(es) that concern tobacco products.

2. Establishment Corporate Affiliations

Identify the corporate structure that the establishment falls under and identify any parent, subsidiary, or other affiliate companies, if applicable. If the establishment is not part of a larger corporate structure, this section may be left blank.

Parent Company Legal Name	Parent Company Physical Address
Subsidiary Company Legal Name	Subsidiary Company Physical Address
Affiliate Company Legal Name	Affiliate Company Physical Address

3. Is the establishment located in a personal residence?

☐ Yes ☐ No

4. Is English the primary language spoken at the establishment?

☐ Yes

☐ No, specify primary language spoken: _____

5. Is the establishment located on Indian Country?

☐ Located on Indian Country – provide name of Tribe: _____

☐ Not located on Indian Country *(Continue below to VIII.A.3)*

A.3 – Updates to Existing Establishment Operations

Instructions for Part A.3 – Updates to Existing Establishment Operations

For the identified establishment, provide updated values for fields that changed. If a field did not change, leave it blank. Submit additional copies for each additional establishment that needs to be updated.

1. Date *(mm/dd/yyyy)* establishment began manufacturing tobacco products for commercial distribution in the U.S.

Note: *specification development is included in manufacturing activities subject to FD&C Act Section 905*

2. Establishment Location *(select one)*

☐ Domestic Establishment

☐ Foreign Establishment

3. Tobacco Product Type(s) Associated With Establishment *(select all that apply)*

☐ Finished Tobacco Products

☐ Consumer Use Bulk Tobacco Products

☐ For Further Manufacturing (FFM)

4. Commercial Distribution Destination of Establishment's Products

☐ Domestic Market *(U.S.)*

☐ Foreign Market *(for Export From U.S.)*

5. Indicate which activities are performed at the registered establishment *(select all that apply)*

General Tobacco Product Manufacturing Activities

☐ Assembling
☐ Compounding
☐ E-Liquid filling/packaging (bottling or pod filling)
☐ E-Liquid production (mixing/blending nicotine, flavorings, PG/VG, or other ingredients)
☐ Formulating
☐ Homogenizing
☐ Labeling
☐ Mixing
☐ Packaging
☐ Preparing
☐ Processing
☐ Relabeling
☐ Repackaging
☐ Specification development for tobacco products
☐ Third-party manufacturing of tobacco products

6. Indicate additional operations performed at the registered establishment *(select all that apply)*

Additional Operations

☐ Distributing Tobacco Products *(specify types of tobacco products distributed)*

- ☐ Cigarettes
- ☐ Cigars
- ☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
- ☐ Heated Tobacco Products (HTP)
- ☐ Pipe Tobacco Products
- ☐ Roll-Your-Own Tobacco Products (RYO)
- ☐ Smokeless Tobacco Products
- ☐ Waterpipe Tobacco Products (Hookah)
- ☐ Oral Nicotine Products
- ☐ Other Tobacco Products *(Specify)*

☐ Importing Tobacco Products *(specify types of tobacco products imported)*

- ☐ Cigarettes
- ☐ Cigars
- ☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
- ☐ Heated Tobacco Products (HTP)
- ☐ Pipe Tobacco Products
- ☐ Roll-Your-Own Tobacco Products (RYO)
- ☐ Smokeless Tobacco Products
- ☐ Waterpipe Tobacco Products (Hookah)
- ☐ Oral Nicotine Products
- ☐ Other Tobacco Products *(Specify)*

☐ Retailing Tobacco Products *(specify types of tobacco products sold)*

- ☐ Cigarettes
- ☐ Cigars
- ☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
- ☐ Heated Tobacco Products (HTP)
- ☐ Pipe Tobacco Products
- ☐ Roll-Your-Own Tobacco Products (RYO)
- ☐ Smokeless Tobacco Products
- ☐ Waterpipe Tobacco Products (Hookah)
- ☐ Oral Nicotine Products
- ☐ Other Tobacco Products *(Specify)*

☐ ENDS Coil or Device Repairs

☐ Storing Tobacco Products

☐ Testing Tobacco Products

☐ Exporting Tobacco Products

☐ Advertising

☐ Other *(Specify)*

A.4 – Updates to Existing Establishment Contact Information

Instructions for Part A.4 – Updates to Existing Establishment Contact Information

Identify the establishment contact whose information has changed since last submission (Identification of Existing Establishment Contact Information to Update) and then provide updated values for fields that changed (Updates to Existing Establishment Contact Information). If a field did not change, leave it blank. Submit additional copies for each additional establishment that needs to be updated.

1. Have there been any changes to the previously provided establishment contact information?

☐ Yes *(continue below to provide the updated establishment contact information)*

☐ No *(skip to Tribe Contact Information, if applicable or proceed to Section VIII.A.5 - Updates to Existing Establishment's Manufacturing Status)*

Identification of Existing Establishment Contact Information to Update

2. First Name	3. Last Name	4. Email Address
		☐ Select if Waiver

5. ☐ Select if the establishment contact identified above needs to be removed and a new establishment contact needs to be added to the existing establishment identified in VIII.A.1 #1-10 above
(*Updated establishment contact information below is for new contact to be added)*

Updates to Existing Establishment Contact Information

6. First Name	7. Middle Initial	8. Last Name

9. Generational Suffix	10. Professional Suffix	11. Position Title

12. Business Name	13. Fax Number

14. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	15. Email Address ☐ Select if Waiver

***Tribe Contact Information** (if establishment affiliated with Tribe)*

16. Have there been any changes to the previously provided establishment Tribe contact information (if on Tribal lands)?
- ☐ Yes *(continue below to provide the updated tribe contact information)*
- ☐ No *(skip to Section VIII.A.5 – Updates to Existing Establishment's Manufacturing Status)*

Identification of Existing Tribe Contact Information to Update

17. First Name	18. Last Name	19. Email Address ☐ Select if Waiver

20. ☐ Select if the Tribe contact identified above needs to be removed and a new Tribe contact needs to be added to the existing establishment identified in VIII.A.1 above. *(Updates to Existing Tribe Contact Information below is for new contact to be added)*

Updates to Existing Tribe Contact Information

21. First Name	22. Middle Initial	23. Last Name

24. Generational Suffix	25. Professional Suffix	26. Position Title

27. Tribe Name	28. Fax Number

29. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	30. Email Address ☐ Select if Waiver

A.5 – Updates to Existing Establishment's Manufacturing Status

1. Have there been changes to the existing registered establishment's manufacturing status since last submission?*
- ☐ Yes *(continue below to provide updated information on manufacturing status)*
- ☐ No *(skip to Section VIII.A.6- New Establishment Registration (if registering new establishment) or IX – Updates to Tobacco Product List Information)*

2. If existing establishment has had a change in manufacturing since last submission (select all that apply)*:

☐ **Existing establishment ceased manufacturing** (all products are no longer commercially distributed)
(skip to Section VIII.A.5.2 – Inactivating Existing Establishment (and Registration, if applicable))

☐ **Existing establishment resumed manufacturing**
(continue below to Section VIII.A.5.1 – Reactivating Existing Establishment)

☐ **Existing establishment transferred manufacturing operations to a different establishment under the same owner** (different establishment on this registration)
(*skip to Section VIII.A.5.2 – Inactivating Existing Establishment (and Registration, if applicable) and Section VIII.A.5.3 – Transferring Manufacturing From Existing Establishment. **Note:** In VIII.A.5.3, identify the establishment that took over manufacturing and update the product-establishment association(s) accordingly in Section IX – Updates to Tobacco Product List Information.)*

☐ **Existing establishment transferred manufacturing operations to a different establishment under different owner** (different establishment on another registration)
*(complete Section VIII.A.5.2 – Inactivating Existing Establishment (and Registration, if applicable) and Section VIII.A.5.3 – Transferring Manufacturing From Existing Establishment below. **Note:** In VIII.A.5.3 if possible, identify the establishment that took over manufacturing operations and the registration ID number (RG ID #) for that establishment and whether they took over manufacturing of all or just some of the products associated with the existing establishment.)*

☐ **Existing establishment transferred manufacturing to a new establishment that needs to be registered**
*(complete Section VIII.A.5.2 – Inactivating Existing Establishment (and Registration, if applicable) and Section VIII.A.5.3 – Transferring Manufacturing From Existing Establishment below. **Note:** In VIII.A.5.3, indicate if this new establishment will be added to this registration or another and when the transfer occurred/will occur.)*

A.5.1 – Reactivating Existing Establishment

Instructions for Part A.5.1 – Reactivating Existing Establishment

If the establishment identified in VIII.A.1 has resumed manufacturing and needs to be reactivated, provide the date manufacturing resumed.

1. Date manufacturing resumed *(mm/dd/yyyy)*:

A.5.2 – Inactivating Existing Establishment (and Registration, if applicable)

Instructions for Part A.5.2 – Inactivating Existing Establishment (and Registration, if applicable)

If the establishment identified in VIII.A.1 has ceased manufacturing and needs to be inactivated, provided the date manufacturing ceased and the reason.

1. Date existing establishment ceased manufacturing activities *(mm/dd/yyyy)*:

Establishment Inactivation Reason

2. If establishment needs to be inactivated select the most appropriate reason below:

☐ **Data Clean-up**
Establishment was included on more than one registration (associated with more than one RG ID #), was erroneously duplicated on the same registration, and/or was included on different registrations at the same address but going by a different name (i.e., legal vs. dba name). If inactivating a duplicate establishment, please provide the RG ID # where the surviving establishment information will be kept up to date.

☐ **Not Engaged in Tobacco Product Manufacturing Activities**
Establishment is still in business but is no longer engaged in tobacco manufacturing activities. This could include switching to retail only, importing and/or distributing without packaging, re-packaging, labeling, or re-labeling, and/or switching to only manufacturing products that are neither tobacco products, nor components or parts of tobacco products.

☐ **Out of Business**
If establishment is no longer in existence in any capacity.

☐ **Other (Specify)**
If inactivating the registration, and therefore the establishments on the registration, use "Other – Registration Inactivation."

Registration Inactivation

3. Was the establishment being inactivated the last remaining active establishment on the registration?

☐ Yes *(continue below to inactivate the whole registration and provide a registration inactivation reason)*

☐ No *(skip to If Inactivating Establishment or Registration for Data Clean-up)*

Registration Inactivation Reason

The purpose of TRLM-NG is to serve as a record of establishments actively involved in the manufacture of tobacco products. If you have no remaining active manufacturing establishments, please inactivate your registration. Note that you must re-activate your registration when you resume tobacco product manufacturing activities or add a new tobacco product manufacturing establishment.

4. If the registration needs to be inactivated, select the most appropriate reason below:

☐ **Data Clean-up**
If different business entities (i.e., owner vs. operator) registered the same establishment at the same address or if instead of transferring the TRLM-NG account management role, a new registration was created to communicate updates to an establishment's information and product list. In the case of duplicate registrations, please indicate the RG ID # of the duplicates and which is the surviving registration that will be kept up to date and confirm the establishments (name, address, and FEI # that should be on the surviving registration).

☐ **Not Engaged in Tobacco Product Manufacturing Activities**
If the establishments on the registration are no longer manufacturing tobacco products (switched to retail, importing, distribution without re-packaging or re-labeling) and thus the registration needs to be inactivated.

☐ **Out of Business**
If the establishments on the registration are no longer in existence in any capacity and the registration needs to be inactivated.

☐ **Other *(Specify)***
If inactivating the registration, and therefore the establishments on the registration, use "Other – Registration Inactivation".

If Inactivating Establishment or Registration for Data Clean-up

If inactivating an establishment citing "Data Clean-Up" identify the duplicate establishment/registration to be inactivated and the establishment/registration to remain active as the surviving duplicate to be maintained and kept up to date.

Identification of Registration and/or Establishment Duplicates

5. If the establishment has a different owner and is on a different registration, you may provide the registration ID number (RG ID #), if known RG _____

6. Establishment Legal Name	7. Establishment DBA Name(s) *(if applicable)*

8. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	9. Establishment D&B DUNS® Number *(if applicable)*

Establishment's Physical Address

10. Street Address Line 1		11. Street Address Line 2 *(Apartment, Suite, Building Number)*	
12. City	13. State, Province, or Territory	14. Country	15. ZIP or Postal Code

Identification of Surviving Registration and/or Establishment to Maintain and Keep Up-To-Date

16. If the establishment has a different owner and is on a different registration, you may provide the registration ID number (RG ID #), if known RG _____

17. Establishment Legal Name	18. Establishment DBA Name(s) *(if applicable)*

19. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	20. Establishment D&B DUNS® Number *(if applicable)*

Surviving Establishment's Physical Address

21. Street Address Line 1		22. Street Address Line 2 *(Apartment, Suite, Building Number)*	
23. City	**24. State, Province, or Territory**	**25. Country**	**26. ZIP or Postal Code**

A.5.3 – Transferring Manufacturing From Existing Establishment

Instructions for Part A.5.3 – Transferring Manufacturing From Existing Establishment

You may use the fields below to provide any available information on where manufacturing transferred to if the existing establishment no longer manufactures, but the products it previously manufactured are still commercially distributed.

If Manufacturing Transferred to a New or Different Establishment

If manufacturing of the listed products transferred to a new or different establishment, identify below the establishment that now manufacturers the listed products.

1. Manufacturing Transferred to *(select one)*

- ☐ **A new establishment to be registered**
  (reference the establishment that will be added to the registration in VIII.A.6.1)
- ☐ **An existing establishment on this registration**
  (reference the other existing establishment on this registration that took over operations for the establishment identified in VIII.A.1)
- ☐ **A different existing establishment on a separate registration (provide details, if available)**
  (reference the RG ID # and establishment name and address where manufacturing transferred to)
- ☐ **A new establishment not currently on a registration (provide details, if available)**
  (reference the RG ID # and establishment name and address where manufacturing transferred to)
- ☐ **Other** *(Specify)*

Identification of New or Different Establishment Manufacturing Transferred To

2. Registration ID Number *(RG ID #)* RG _____

3. Establishment Legal Name	4. Establishment DBA Name(s) *(if applicable)*

5. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Establishment D&B DUNS® Number *(if applicable)*

7. Establishment identified above took over manufacturing of *(select one)*

- ☐ All products previously associated to the establishment identified in IV.A.1
- ☐ Some of the products associated to the establishment identified in IV.A.1
  (indicate which products need to be inactivated and which ones need to be reassociated to the establishment above in Section IX – Updates to Tobacco Product List Information.)

8. Date establishment took over manufacturing activities *(mm/dd/yyyy)*:

New or Different Establishment's Physical Address that Manufacturing Transferred To			
9. Street Address Line 1*		10. Street Address Line 2 *(Apartment, Suite, Building Number)*	
11. City	12. State, Province, or Territory	13. Country	14. ZIP or Postal Code

A.6 – New Establishment Registration

A.6.1 – Information for New Establishment to Be Registered

Instructions for Part A.6.1 – Information for New Establishment to Be Registered

Provide information on the new establishment to be added to the registration. Make sure to add any new products or associate previously listed products for this establishment in Section IX – Updates to Tobacco Product List Information

New Establishment Information		
1. Establishment Legal Name*	2. Does the establishment do business by any other name?* ☐ Yes *(continue to VIII.A.6.1 #3)* ☐ No *(skip to VIII.A.6.1 #4)*	3. Establishment DBA Name(s) *(if applicable)*
4. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*		5. Establishment D&B DUNS® Number *(if applicable)*

New Establishment Physical Address			
6. Street Address Line 1*		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.A.6.2: Details for New Establishment to Be Registered.

New Establishment Mailing Address			
13. Street Address Line 1*		14. Street Address Line 2 *(Apartment, Suite, Building Number)*	
15. City*	16. State, Province, or Territory*	17. Country*	18. ZIP or Postal Code*

A.6.2 – Details for New Establishment to Be Registered

1. Provide the establishment's website address(es) that concern tobacco products.*

2. Establishment Corporate Affiliations

Identify the corporate structure that the establishment falls under and identify any parent, subsidiary, or other affiliate companies, if applicable. If the establishment is not part of a larger corporate structure, this section may be left blank.

Parent Company Legal Name	Parent Company Physical Address
Subsidiary Company Legal Name	Subsidiary Company Physical Address
Affiliate Company Legal Name	Affiliate Company Physical Address

3. Is the establishment located in a personal residence?

☐ Yes ☐ No

4. Is English the primary language spoken at the establishment?

☐ Yes

☐ No, specify primary language spoken: _____

5. Is the establishment located on Indian Country?

☐ Located on Indian Country – provide name of Tribe: _____

☐ Not located on Indian Country *(continue below to Section VIII.A.6.3 – Operations for New Establishment to be Registered)*

A.6.3 – Operations for New Establishment to be Registered

1. Date *(mm/dd/yyyy)* establishment began manufacturing tobacco products for commercial distribution in the U.S.*

***Note**: specification development is included in manufacturing activities subject to FD&C Act Section 905*

2. Establishment Location *(select one)*	3. Tobacco Product Type(s) Associated with Establishment *(select all that apply)**	4. Commercial Distribution Destination of Establishment's Products
☐ Domestic Establishment ☐ Foreign Establishment	☐ Finished Tobacco Products ☐ Consumer Use Bulk Tobacco Products ☐ For Further Manufacturing (FFM)	☐ Domestic Market *(U.S.)* ☐ Foreign Market *(for Export From U.S.)*

5. Indicate which manufacturing activities are performed at the registered establishment *(select all that apply)**

General Tobacco Product Manufacturing Activities

☐ Assembling
☐ Compounding
☐ E-Liquid filling/packaging (bottling or pod filling)
☐ E-Liquid production (mixing/blending nicotine, flavorings, PG/VG, or other ingredients)
☐ Formulating
☐ Homogenizing
☐ Labeling
☐ Mixing
☐ Packaging
☐ Preparing
☐ Processing
☐ Relabeling
☐ Repackaging
☐ Specification development for tobacco products
☐ Third-party manufacturing of tobacco products

6. Indicate additional operations performed at the registered establishment *(select all that apply)*

Additional Operations

☐ Distributing Tobacco Products *(specify types of tobacco products distributed)*

☐ Cigarettes
☐ Cigars
☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
☐ Heated Tobacco Products (HTP)
☐ Pipe Tobacco Products
☐ Roll-Your-Own Tobacco Products (RYO)
☐ Smokeless Tobacco Products
☐ Waterpipe Tobacco Products (Hookah)
☐ Oral Nicotine Products
☐ Other Tobacco Products *(Specify)* _____

☐ Importing Tobacco Products *(specify types of tobacco products imported)*

- ☐ Cigarettes
- ☐ Cigars
- ☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
- ☐ Heated Tobacco Products (HTP)
- ☐ Pipe Tobacco Products
- ☐ Roll-Your-Own Tobacco Products (RYO)
- ☐ Smokeless Tobacco Products
- ☐ Waterpipe Tobacco Products (Hookah)
- ☐ Oral Nicotine Products
- ☐ Other Tobacco Products *(Specify)*

☐ Retailing Tobacco Products *(specify types of tobacco products sold)*

- ☐ Cigarettes
- ☐ Cigars
- ☐ Electronic Nicotine Delivery Systems (ENDS)/(Vapes)
- ☐ Heated Tobacco Products (HTP)
- ☐ Pipe Tobacco Products
- ☐ Roll-Your-Own Tobacco Products (RYO)
- ☐ Smokeless Tobacco Products
- ☐ Waterpipe Tobacco Products (Hookah)
- ☐ Oral Nicotine Products
- ☐ Other Tobacco Products *(Specify)*

☐ ENDS Coil or Device Repairs

☐ Storing Tobacco Products

☐ Testing Tobacco Products

☐ Exporting Tobacco Products

☐ Advertising

☐ Other *(Specify)*

A.6.4 – Establishment Contact Information

Instructions for Part A.6.4 – Establishment Contact Information

Provide contact information for each establishment to be registered. Use additional copies of this part for each additional establishment being registered.

Contact Information for New Establishment to Be Registered

1. First Name*	2. Middle Initial	3. Last Name*
4. Generational Suffix	5. Professional Suffix	6. Position Title*
7. Business Name*		8. Fax Number
9. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile		10. Email Address ☐ Select if Waiver

Tribe Contact Information *(if establishment affiliated with Tribe)*

11. First Name	12. Middle Initial	13. Last Name
14. Generational Suffix	15. Professional Suffix	16. Position Title
17. Tribe Name		18. Fax Number

19. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	20. Email Address ☐ Select if Waiver

Part B: Updates to Establishment Owner Information

Instructions for Part B – Updates to Establishment Owner Information

Provide details on the owners of the registered establishment.

Confirm whether there have been any changes to the registered establishment's owner information since the last submission. If so, identify the owner whose information needs to be updated and provide the updated values for the fields that changed. Submit additional copies of this section as needed for each additional owner that needs to be updated or added.

Note: *At a minimum to identify the owner business that needs to be updated, provide the business name and physical address. If contact information for the owner needs to be updated or removed, provide a name and email address. If a new owner needs to be added to the registration, provide the same information required for initial owner registration (per Section IV. Part B).*

1. Have there been any changes to the owner information for any of the registered establishments since the last submission? *(select one)**

☐ Yes *(continue below to provide information on the owner information changes)*

☐ No *(proceed to Section VIII.C – Updates to Operator Information)*

2. Select the appropriate summary of the change needed and follow the prompts accordingly *(select all that apply)*

☐ **Updating existing owner business information** *(Provide updated values for fields that changed in VIII.B.1)*

☐ **Updating existing owner business structure** *(Provide updated values for fields that changed in VIII.B.2)*

☐ **Updating existing owner contact information** *(Provide updated values for fields that changed in VIII.B.3)*

☐ **Adding new owner business information, business structure, and contact information (replaces all previous owner information)** *(Provide new owner information in VIII.B.4)*

3. Effective Date of Change *(mm/dd/yyyy):*

B.1 – Updates to Existing Owner's Business Information

1. Owner's Business Legal Name	2. Does the owner's business go by any other name? ☐ Yes *(continue to VIII.B.1.#3)* ☐ No *(skip to VIII.B.1 #4)*	3. Owner's Business DBA Name(s) *(if applicable)*

4. Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*

Updates to Existing Owner's Business Physical Address

6. Street Address Line 1	7. Street Address Line 2 *(Apartment, Suite, Building Number)*

8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.B.2 – Updates to Existing Owner's Business Structure

Updates to Existing Owner's Business Mailing Address

13. Street Address Line 1	14. Street Address Line 2 *(Apartment, Suite, Building Number)*

15. City	16. State, Province, or Territory	17. Country	18. ZIP or Postal Code

B.2 – Updates to Existing Owner's Business Structure

1. Select the type of business structure most applicable to the owner's business *(select one)*

☐ **Sole Proprietorship** *(provide information for the individual owner)*

☐ **Partnership** *(provide information on each partner)*

☐ **Corporation**, **Including Limited Liability** *(enter information on each corporate officer and director)*

2. Provide the indicated information for each key official within the owner's business structure

Corporate Officer and/or Company Official #1

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #2

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #3

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #4

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #5

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #6

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Location of Formation of Legal Business Entity

3. Identify the state, territory, or possession of formation *(if in the U.S.)* or the country of incorporation *(if outside the U.S.)**

B.3 – Updates to Existing Owner's Contact Information

Instructions for Part B.3 – Updates to Existing Owner's Contact Information

Provide contact information for the owner of the establishment to be registered

1. Have there been any changes to the previously provided owner contact information? *(select one)*
   - ☐ Yes *(continue below to provide information. Leave blank any field that did not change since last submission)*
   - ☐ No *(skip to Section VIII.C – Updates to Establishment Operator Information)*

2. First Name	3. Middle Initial	4. Last Name

5. Generational Suffix	6. Professional Suffix	7. Position Title

8. Business Name	9. Fax Number

10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	11. Email Address ☐ Select if Waiver

B.4 – New Owner's Information

Instructions for Part B.4 – New Owner's Information

Provide details on the new owner of the registered establishment(s).

B.4.1 – New Owner's Business Information

1. Owner's Business Legal Name*	2. Does the owner's business go by any other name?* ☐ Yes *(continue to VIII.B.4.1.#3)* ☐ No *(skip to VIII.B.4.1 #4)*	3. Owner's Business DBA Name(s) *(if applicable)*

4. Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*

New Owner's Business Physical Address

6. Street Address Line 1*	7. Street Address Line 2 *(Apartment, Suite, Building Number)*

8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.B.4.2 – New Owner's Business Structure.

New Owner's Business Mailing Address

13. Street Address Line 1*	14. Street Address Line 2 *(Apartment, Suite, Building Number)*

15. City*	16. State, Province, or Territory*	17. Country*	18. ZIP or Postal Code*

B.4.2 – New Owner's Business Structure

1. Select the type of business structure most applicable to the owner's business *(select one)**

☐ **Sole Proprietorship** *(provide information for the individual owner)*
☐ **Partnership** *(provide information on each partner)*
☐ **Corporation**, **Including Limited Liability** *(enter information on each corporate officer and director)*

2. Provide the indicated information for each key official within the owner's business structure

Corporate Officer and/or Company Official #1

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #2

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #3

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #4

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #5

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #6

First Name*	Middle Initial	Last Name*	
Generational Suffix	Professional Suffix	Position Title	Business Name

Location of Formation of Legal Business Entity

3. Identify the state, territory, or possession of formation *(if in the U.S.)* or the country of incorporation *(if outside the U.S.)**

B.4.3 – New Owner's Contact Information

Instructions for Part B.4.3 – New Owner's Contact Information

Provide contact information for the new owner of the establishment

1. First Name*	2. Middle Initial	3. Last Name*

4. Generational Suffix	5. Professional Suffix	6. Position Title

7. Business Name*	8. Fax Number

9. Phone Number *(select one and provide number)**	10. Email Address*
☐ Work ☐ Mobile	☐ Select if Waiver

Part C – Updates to Establishment Operator Information

Instructions for Part C – Updates to Establishment Operator Information

Provide details on the operator of the registered establishment.

Confirm whether there have been any changes to the registered establishment's operator information since the last submission. If so, identify the operator whose information needs to be updated and provide the updated values for the fields that changed. Submit additional copies of this section as needed for each additional operator that needs to be updated or added.

Note: *At a minimum to identify the owner business that needs to be updated, provide the business name and physical address. If contact information for the operator needs to be updated or removed, provide a name and email address. If a new operator needs to be added to the registration, provide the same information required for initial operator registration (per Section IV, Part C).*

1. Have there been any changes to the operator information for any of the registered establishments since the last submission? *(select one)**

   ☐ Yes *(continue below to provide information on the operator information changes)*

   ☐ No *(proceed to Section VIII.D – Updates to Brand Owner Information)*

2. Select the appropriate summary of the change needed and follow the prompts accordingly *(select all that apply)*

   ☐ **Updating existing operator business information** *(Provide updated values for fields that changed in VIII.C.1)*

   ☐ **Updating existing operator business structure** *(Provide updated values for fields that changed in VIII.C.2)*

   ☐ **Updating existing operator contact information** *(Provide updated values for fields that changed in VIII.C.3)*

   ☐ **Removing operator** *(Identify the operator to be removed, if there are more than one.)*
   Note: *registration must have at least one operator, if this is selected and there was only one operator in your registration, you will be prompted to provide a new operator to replace it in VIII.C.4.*

   ☐ **Adding new operator business information, business structure, and contact information** *(Provide new operator information in VIII.C.4)*

3. Effective Date of Change *(mm/dd/yyyy):*

Identification of Existing Operator to Update or Remove

4. Operator's Business Legal Name	5. Operator's Business DBA Name(s) *(if applicable)*

6. Operator's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	7. Operator's Business Headquarters' D&B DUNS® Number *(if applicable)*

Physical Address of Existing Operator's Business to Update or Remove

8. Street Address Line 1		9. Street Address Line 2 *(Apartment, Suite, Building Number)*	
10. City	11. State, Province, or Territory	12. Country	13. ZIP or Postal Code

Identification of Existing Operator's Contact to Update or Remove

14. First Name	15. Last Name	16. Email Address ☐ Select if Waiver

C.1 – Updates to Existing Operator's Business Information

1. Operator's Business Legal Name	2. Does the operator's business go by any other name? ☐ Yes *(continue to VIII.C.1 #3)* ☐ No *(skip to VIII.C.1 #4)*	3. Operator's Business DBA Name(s) *(if applicable)*

4. Operator's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Operator's Business Headquarters' D&B DUNS® Number *(if applicable)*

Updates to Existing Operator's Business Physical Address

6. Street Address Line 1		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.C.2 – Updates to Operator's Business Structure.

Updates to Existing Operator's Business Mailing Address

13. Street Address Line 1		14. Street Address Line 2 *(Apartment, Suite, Building Number)*	
15. City	16. State, Province, or Territory	17. Country	18. ZIP or Postal Code

C.2 – Updates to Existing Operator's Business Structure

1. Select the type of business structure most applicable to the operator's business *(select one)*

☐ **Sole Proprietorship** *(provide information for the individual owner)*
☐ **Partnership** *(provide information on each partner)*
☐ **Corporation**, **Including Limited Liability** *(enter information on each corporate officer and director)*

2. Provide the indicated information for each key official within the operator's business structure

Corporate Officer and/or Company Official #1

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #2

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #3

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #4

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #5

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #6

First Name	Middle Initial	Last Name

Generational Suffix	Professional Suffix	Position Title	Business Name

Location of Formation of Legal Business Entity

3. Identify the state, territory, or possession of formation *(if in the U.S.)* or the country of incorporation *(if outside the U.S.)**

C.3 – Updates to Existing Operator's Contact Information

Provide contact information for the operator of the establishment to be registered

1. Have there been any changes to the operator information for any of the registered establishments since the last submission? *(select one)*

☐ Yes *(continue below to provide information. Leave blank any field that did not change since last submission)*

☐ No *(proceed to Section VIII.D – Updates to Brand Owner Information)*

2. First Name	3. Middle Initial	4. Last Name

5. Generational Suffix	6. Professional Suffix	7. Position Title

8. Business Name	9. Fax Number

10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	11. Email Address ☐ Select if Waiver

C.4 – New Operator's Information

Provide details on the new operator of the registered establishment(s).

C.4.1 – New Operator's Business Information

1. Operator's Business Legal Name*	2. Does the operator's business go by any other name?* ☐ Yes *(continue to VIII.C.4.1 #3)* ☐ No *(skip to VIII.C.4.1 #4)*	3. Operator's Business DBA Name(s) *(if applicable)*

4. Operator's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Operator's Business Headquarters' D&B DUNS® Number *(if applicable)*

New Operator's Business Physical Address

6. Street Address Line 1*	7. Street Address Line 2 *(Apartment, Suite, Building Number)*

8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

12. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.C.4.2 – New Operator's Business Structure.

New Operator's Business Mailing Address

13. Street Address Line 1*	14. Street Address Line 2 *(Apartment, Suite, Building Number)*

15. City*	16. State, Province, or Territory*	17. Country*	18. ZIP or Postal Code*

C.4.2 – New Operator's Business Structure

1. Select the type of business structure most applicable to the operator's business *(select one)**

☐ **Sole Proprietorship** *(provide information for the individual owner of the operator's business)*
☐ **Partnership** *(provide information on each partner)*
☐ **Corporation**, **Including Limited Liability** *(enter information on each corporate officer and director)*

2. Provide the indicated information for each key official within the operator's business structure

Corporate Officer and/or Company Official #1

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #2

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #3

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #4

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #5

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Corporate Officer and/or Company Official #6

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title	Business Name

Location of Formation of Legal Business Entity

3. Identify the state, territory, or possession of formation *(if in the U.S.)* or the country of incorporation *(if outside the U.S.)**

C.4.3 – New Operator's Contact Information

Instructions for Part C.4.3 – New Operator's Contact Information

Provide contact information for the new operator of the establishment

1. First Name*	2. Middle Initial	3. Last Name*

4. Generational Suffix	5. Professional Suffix	6. Position Title

7. Business Name*	8. Fax Number

9. Phone Number *(select one and provide number)** ☐ Work ☐ Mobile	☐ Select if Waiver

Part D – Updates to Brand Owner Information

Instructions for Part D – Updates to Brand Owner Information

You may use the fields below to provide details on who owns a brand, through creation, acquisition, trademark, patent, copyright, or otherwise, and has directly or through license, the control and/or direction of the brand(s) manufactured at the establishment being registered.

Confirm whether there have been any changes to the registered establishment's brand owner information and affiliated brand owners for the tobacco products manufactured at the establishment since last submission. If so, you may identify the brand owner whose information needs to be updated and provide the updated values for the fields that changed. You may submit additional copies of this section as needed for each additional brand owner that needs to be updated or added.

Note: *At a minimum to identify the brand owner business that needs to be updated, provide the business name and physical address. If contact information for the brand owner needs to be updated or removed, provide a name and email address. If a new brand owner needs to be added to the registration, provide the same information required for initial brand owner submission (per Section IV, Part D).*

Note: *While the below fields in this Part are not required to complete registration, completing this Part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding brand owner information.*

1. Have there been any changes to the brand owner information for any of the registered establishments since the last submission? *(select one)*

   ☐ Yes *(continue below to provide information on the brand owner information changes)*

   ☐ No *(proceed to Section VIII.E – Updates to Direct Account Information)*

2. Select the appropriate summary of the change needed and follow the prompts accordingly *(select all that apply)*

   ☐ **Updating existing establishment's brand owner status**
   (Provide updated values for fields that changed in VIII.D.1)

   ☐ **Updating existing brand owner business information**
   (Provide updated values for fields that changed in VIII.D.2)

   ☐ **Updating existing brand owner contact information**
   (Provide updated values for fields that changed in VIII.D.3)

   ☐ **Removing brand owner**
   (Identify the brand owner to be removed, if there are more than one)

   ☐ **Adding new brand owner status, business information, and contact information**
   (Provide new owner information in VIII.D.4)

3. Effective Date of Change *(mm/dd/yyyy):*

Identification of Existing Brand Owner Information to Update or Remove

4. Brand Owner's Business Legal Name	5. Brand Owner's Business DBA Name(s) *(if applicable)*

6. Brand Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	7. Brand Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*

Identification of Existing Brand Owner's Business Physical Address to Update or Remove

8. Street Address Line 1		9. Street Address Line 2 *(Apartment, Suite, Building Number)*	
10. City	11. State, Province, or Territory	12. Country	13. ZIP or Postal Code

Identification of Existing Brand Owner's Contact to Update or Remove

14. First Name	15. Last Name	16. Email Address

D.1 – Updates to Existing Establishment's Brand Owner Status

1. Does the registered establishment indicated above own some, all, or none of the product brands on its product list? (i.e*., is the registered establishment also the product brand owner). (select one)*

☐ **Has ownership over <u>all</u> product brands**
Establishment to be registered is also the product brand owner for all products manufactured
(proceed to Section VIII.E – Updates to Direct Account Information)

☐ **Has ownership over <u>some</u> product brands**
Establishment to be registered owns some, not all, of the product brands manufactured *(continue below)*

☐ **Has ownership over <u>none</u> of the product brands**
Establishment to be registered has no ownership of any of the product brands manufactured *(skip to VIII D.2 #1)*

2. Which product brands manufactured at the establishment does the establishment being registered have brand ownership of?

3. Which product brands manufactured at the establishment does the establishment being registered **<u>not</u>** have brand ownership of? *(provide brand owner information)*

D.2 – Updates to Brand Owner's Business Information

1. Brand Owner's Business Legal Name	2. Does the brand owner's business go by any other name? ☐ Yes *(continue to VIII.D.2 #3)* ☐ No *(skip to VIII.D.1 #4)*	3. Brand Owner's Business DBA Name(s) *(if applicable)*

4. Brand Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Brand Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*

6. What brands are owned by this brand owner as they pertain to products manufactured at this establishment?

Updates to Existing Brand Owner's Business Physical Address

7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.D.3 – Updates to Brand Owner's Contact Information.

Updates to Existing Brand Owner's Business Mailing Address

14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

D.3 – Updates to Brand Owner's Contact Information

1. First Name	2. Middle Initial	3. Last Name
4. Generational Suffix	5. Professional Suffix	6. Position Title
7. Business Name		8. Fax Number

9. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	10. Email Address ☐ Select if Waiver

D.4 – New Brand Owner Information

Instructions for Part D.4 – New Brand Owner Information

You may provide details on the new brand owner(s) associated with the registered establishment(s). Submit additional copies for his part for each additional brand owner to add.

D.4.1 – New Brand Owner Status Existing Establishment

1. Does the registered establishment own some, all, or none of the product brands on its product list? (i.e., is the registered establishment also the product brand owners). *(select one)*

☐ **Has ownership over <u>all</u> product brands**
Establishment to be registered is also the product brand owner for all products manufactured *(proceed to Section VIII.E – Updates to Direct Account(s) Information)*

☐ **Has ownership over <u>some</u> product brands**
Establishment to be registered owns some, not all, of the product brands manufactured *(continue below)*

☐ **Has ownership over <u>none</u> of the product brands**
Establishment to be registered has no ownership of any of the product brands manufactured *(skip to VIII.D.4.2)*

2. Which product brands manufactured at the establishment does the establishment being registered have brand ownership of?

3. Which product brands manufactured at the establishment does the establishment being registered **<u>not</u>** have brand ownership of? *(provide brand owner information)*

D.4.2 – New Brand Owner's Business Information

1. Brand Owner's Business Legal Name	2. Does the brand owner's business go by any other name? ☐ Yes *(continue to VIII.D.4.2 #3)* ☐ No *(skip to VIII.D.4.2 #4)*	3. Brand Owner's Business DBA Name(s) *(if applicable)*

4. Brand Owner's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Brand Owner's Business Headquarters' D&B DUNS® Number *(if applicable)*

6. What brands are owned by this brand owner as they pertain to products manufactured at this establishment?

New Brand Owner's Business Physical Address

7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.D.4.3 – New Brand Owner's Contact Information.

Updates to Existing Brand Owner's Business Mailing Address

14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

D.4.3 – New Brand Owner's Contact Information

1. First Name	2. Middle Initial	3. Last Name
4. Generational Suffix	5. Professional Suffix	6. Position Title
7. Business Name		8. Fax Number
9. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile		10. Email Address ☐ Select if Waiver

Part E – Updates to Direct Account(s) Information

Instructions for Part E – Updates to Direct Account(s) Information

You may use the fields below to provide details on the registered establishment's direct account(s). Examples of direct account(s) for registered finished product manufacturing establishments include retailers, distributors, and wholesalers. An example of a direct account for bulk tobacco product manufacturing establishments would be the finished product manufacturer that receives the bulk tobacco products for further manufacturing into a finished tobacco product. An example of a direct account for product specification developing establishments would be the manufacturing establishment that further manufactures the products to the specifications developed. You may submit additional sections for each additional direct account.

Note: *At a minimum to identify the direct account business that needs to be updated, provide the direct account business name and physical address. If contact information for the direct account needs to be updated or removed, provide a name and email address. If a new direct account needs to be added to the registration, provide the same information as prompted for initial direct account submission (per Section IV, Part D).*

Note: *While the below fields in this Part are not required to complete registration, completing this Part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding direct account information.*

1. Have there been any changes to the direct account information for any of the registered establishments since the last submission? *(select one)*

☐ Yes *(continue below to provide information on the direct account information changes)*

☐ No *(proceed to Section VIII, Part F – Updates to Importer(s)/Consignee(s) Information)*

2. Select the appropriate summary of the change needed and follow the prompts accordingly *(select all that apply)*

☐ **Updating existing direct account business information**
(Provide updated values for fields that changed in VIII.E.1)

☐ **Updating existing direct account contact information**
(Provide updated values for fields that changed in VIII.E.2)

☐ **Removing direct account**
(Identify the direct account to be removed, if there are more than one)

☐ **Adding new direct account status, business information, and contact information**
(Provide new direct account information in VIII.E.3)

3. Effective Date of Change *(mm/dd/yyyy):*

Identification of Existing Direct Account Business Information to Update or Remove

4. Direct Account is *(select one)*

☐ Retailer
☐ Distributor
☐ Wholesaler
☐ Finished Product Manufacturer
☐ Other *(Specify)*

5. Direct Account's Business Legal Name	6. Direct Account's Business DBA Name(s) *(if applicable)*
7. Direct Account's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	8. Direct Account's Business Headquarters' D&B DUNS® Number *(if applicable)*

Identification of Existing Direct Account's Business Physical Address to Update or Remove

9. Street Address Line 1		10. Street Address Line 2 *(Apartment, Suite, Building Number)*	
11. City	12. State, Province, or Territory	13. Country	14. ZIP or Postal Code

Identification of Existing Direct Account's Contact to Update or Remove

15. First Name	16. Last Name	17. Email Address ☐ Select if Waiver

E.1 – Updates to Existing Direct Account's Business Information

1. Direct Account is *(select one)*
   - ☐ Retailer
   - ☐ Distributor
   - ☐ Wholesaler
   - ☐ Finished Product Manufacturer *(if registered establishment was bulk tobacco product manufacturer)*
   - ☐ Other *(Specify)* _____

2. Direct Account's Business Legal Name	3. Does the direct account's business go by any other name? ☐ Yes *(continue to VIII.E.1 #4)* ☐ No *(skip to VIII.E.1 #5)*	4. Direct Account's Business DBA Name(s) *(if applicable)*

5. Direct Account's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Direct Account's D&B DUNS® Number *(if applicable)*

Updates to Existing Direct Account's Physical Address

7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII. E.2: Direct Account's Contact Information.

Updates to Existing Direct Account's Mailing Address

14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

E.2 – Updates to Existing Direct Account Contact Information

1. Have there been any changes to the previously provided direct account contact information? *(select one)*
   - ☐ Yes *(continue below to provide information. Leave blank any field that did not change since last submission)*
   - ☐ No *(skip to Section VIII.E.3 – New Direct Account Information or proceed to Section VIII, Part F)*

2. First Name	3. Middle Initial	4. Last Name

5. Generational Suffix	6. Professional Suffix	7. Position Title

8. Business Name	9. Fax Number

10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	11. Email Address ☐ Select if Waiver

E.3 – New Direct Account Information

Instructions for Part E.3 – New Direct Account Information

You may provide details on the new direct account(s) associated with the registered establishment(s). Submit additional copies for this part for each additional direct account to add.

E.3.1 – New Direct Account Business Information

1. Direct Account is *(select one)*

- ☐ Retailer
- ☐ Distributor
- ☐ Wholesaler
- ☐ Finished Product Manufacturer *(if registered establishment was bulk tobacco product manufacturer)*
- ☐ Other *(Specify)*

New Direct Account Business Information

2. Direct Account's Business Legal Name	3. Does the direct account's business go by any other name? ☐ Yes *(continue to IV.E.2 #4)* ☐ No *(skip to IV.E.2 #5)*	4. Direct Account's Business DBA Name(s) *(if applicable)*

5. Direct Account's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Direct Account's D&B DUNS® Number *(if applicable)*

New Direct Account's Physical Address

7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.E.3.2 – New Direct Account's Contact Information

New Direct Account's Mailing Address

14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

E.3.2 – New Direct Account's Contact Information

1. First Name	2. Middle Initial	3. Last Name

4. Generational Suffix	5. Professional Suffix	6. Position Title

7. Business Name	8. Fax Number

9. Phone Number *(select one and provide number)*	10. Email Address
☐ Work ☐ Mobile	☐ Select if Waiver

Part F – Updates to Establishment Importer(s) and Consignee(s) Information

Instructions for Part F – Updates to Establishment Importer(s) and Consignee(s) Information

Confirm whether there have been any changes to the registered establishment's importer/consignee information since last submission. If so, you may use the fields below to identify the importer or consignee business or contact information that needs to be updated, removed, or if a new importer/consignee needs to be added. You may submit additional copies of this section as needed for each additional importer or consignee that needs to be updated, removed, or added.

Note: *At a minimum to identify the importer/consignee business that needs to be updated, provide the importer/consignee business name and physical address. If contact information for the importer/consignee needs to be updated or removed, provide a name and email address. If a new importer/consignee needs to be added to the registration, provide the same information as prompted for initial importer/consignee submission (per Section IV, Part E).*

Note: *While the below fields in this Part are not required to complete registration, completing this Part could lessen or eliminate the need for additional resources being dedicated by the establishment to respond to future information requests from FDA regarding importer/consignee information.*

1. Have there been any changes to the importer/consignee information for any of the registered establishments since the last submission? *(select one)*
   - ☐ Yes *(continue below to provide information on the importer/consignee information changes)*
   - ☐ No *(proceed to Section IX – Updates to Tobacco Product List Information)*

2. Select the appropriate summary of the change needed and follow the prompts accordingly *(select all that apply)*
   - ☐ **Updating existing importer/consignee business information**
     (Provide updated values for fields that changed in VIII.F.1)
   - ☐ **Updating existing importer/consignee contact information**
     (Provide updated values for fields that changed in VIII.F.2)
   - ☐ **Removing importer/consignee**
     (Identify the importer/consignee to be removed, if there are more than one)
   - ☐ **Adding new importer/consignee reporting status, business information, and contact information**
     (Provide new owner information in VIII.F.3)

3. Effective Date of Change *(mm/dd/yyyy):*

Identification of Existing Importer/Consignee to Update or Remove

4. Business and contact information indicated below are for establishment's *(select one)*
   - ☐ Importer
   - ☐ Consignee
   - ☐ Both *(registered establishment's importer is also the consignee)*

5. Importer/Consignee's Business Legal Name	6. Importer/Consignee's Business DBA Name(s) *(if applicable)*
7. Importer/Consignee's Business Headquarters' FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	8. Importer/Consignee's Business Headquarters' D&B DUNS® Number *(if applicable)*

Identification of Existing Importer/Consignee's Business Physical Address to Update or Remove

9. Street Address Line 1	10. Street Address Line 2 *(Apartment, Suite, Building Number)*

11. City	12. State, Province, or Territory	13. Country	14. ZIP or Postal Code

Identification of Existing Importer/Consignee's Contact Information to Update or Remove

15. First Name	16. Last Name	17. Email Address ☐ Select if Waiver

F.1 – Updates to Existing Importer/Consignee's Business Information

1. Business information indicated below are for establishment's *(select one)*

☐ Importer
☐ Consignee
☐ Both *(registered establishment's importer is also the consignee)*

2. Importer/Consignee's Business Legal Name	3. Does the importer/consignee's business go by any other name? ☐ Yes *(continue to VIII.F.1 #4)* ☐ No *(skip to VIII.F.1 #5)*	4. Importer/Consignee's Business DBA Name(s) *(if applicable)*

5. Importer/Consignee's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Importer/Consignee's D&B DUNS® Number *(if applicable)*

Updates to Existing Importer/Consignee's Business Physical Address

7. Street Address Line 1	8. Street Address Line 2 *(Apartment, Suite, Building Number)*

9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.F.2 – Updates to Existing Importer/Consignee's Contact Information.

Updates to Existing Importer/Consignee's Business Mailing Address

14. Street Address Line 1	15. Street Address Line 2 *(Apartment, Suite, Building Number)*

16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

F.2 – Updates to Existing Importer/Consignee's Contact Information

1. Contact information below is for: *(select one)*

☐ Importer ☐ Consignee ☐ Both

Updates to Existing Importer/Consignee's Contact Information

2. First Name	3. Middle Initial	4. Last Name

5. Generational Suffix	6. Professional Suffix	7. Position Title

8. Business Name	9. Fax Number

10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	11. Email Address ☐ Select if Waiver

F.3 – New Importer/Consignee's Business Information

Instructions for Part F.3 – New Importer/Consignee's Business Information

You may provide details on the new importer/consignee associated with the registered establishment(s). Submit additional copies for this part for each additional importer/consignee to add.

F.3.1 – New Importer/Consignee's Business Information

1. Business information indicated below are for establishment's *(select one)*

☐ Importer
☐ Consignee
☐ Both *(registered establishment's importer is also the consignee)*

2. Importer/Consignee's Business Legal Name	3. Does the importer/consignee's business go by any other name? ☐ Yes *(continue to VIII.F.3.1 #4)* ☐ No *(skip to VIII.F.3.1 #5)*	4. Importer/Consignee's Business DBA Name(s) *(if applicable)*

5. Importer/Consignee's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	6. Importer/Consignee's D&B DUNS® Number *(if applicable)*

New Importer/Consignee's Business Physical Address

7. Street Address Line 1		8. Street Address Line 2 *(Apartment, Suite, Building Number)*	
9. City	10. State, Province, or Territory	11. Country	12. ZIP or Postal Code

13. ☐ Select if mailing address is same as physical address. If the same, skip to Section VIII.F.3.2 – New Importer/Consignee's Contact Information

New Importer/Consignee's Business Mailing Address

14. Street Address Line 1		15. Street Address Line 2 *(Apartment, Suite, Building Number)*	
16. City	17. State, Province, or Territory	18. Country	19. ZIP or Postal Code

F.3.2 – New Importer/Consignee's Contact Information

1. Contact information below is for: *(select one)*

☐ Importer ☐ Consignee ☐ Both

New Importer/Consignee's Contact Information

2. First Name	3. Middle Initial	4. Last Name

5. Generational Suffix	6. Professional Suffix	7. Position Title

8. Business Name	9. Fax Number

10. Phone Number *(select one and provide number)* ☐ Work ☐ Mobile	11. Email Address ☐ Select if Waiver

SECTION IX – UPDATES TO TOBACCO PRODUCT LIST INFORMATION

Instructions for Section IX – Updates to Tobacco Product List Information

Confirm whether there have been any changes to the Tobacco Product List since last submission, indicate the type of change (i.e., adding new tobacco product, updating existing product information, updating product marketing authorization status, etc.), identify each tobacco product impacted by the change, and provide the updated new values for the impacted fields. Leave the field blank where there has been no updates to report since the last submission. Submit additional copies of this section for each additional tobacco product that a change needs to be reported for.

If a new product(s) need to be added to the product list, provide the same information required for initial product list submissions per Section V and provide sufficient establishment identifiers to identify the establishment(s) that need to be associated to the new product.

If updating a previously listed tobacco product, identify the tobacco product to update (i.e., name (including brand and subbrand), UPC, alternative industry product identification number (if no UPC), TP #).

Note: *Only changes to the tobacco product list are to be reported. Any modification made to a tobacco product must be reported through the appropriate notice, application, or request in accordance with the FD&C Act and its implementing regulations.*

1. Have there been any changes to the product list since the last submission? *(select one)**

☐ Yes *(continue below to provide information on the product list changes)*

☐ No *(proceed to Section X – Updates to Labeling, Advertising, Consumer Information (Material Files))*

2. Select the appropriate summary of the change needed *(select all that apply)*

☐ **Updating product information for previously listed product**
(Provide the effective date of change (#3 below), identify the existing product to update (in #4 –12 below), and provide updated values in Part A-D, then proceed to Section X – Updates to Labeling, Advertising, Consumer Information (Material File))

☐ **Inactivating previously listed tobacco product removed from commercial distribution**
(Provide the effective date of change (#3 below), identify the existing product to inactivate (in #4-12 below), and proceed to Section X – Updates to Labeling, Advertising, Consumer Information (Material File))

☐ **Reactivating previously listed tobacco product reintroduced into commercial distribution**
(Provide the effective date of change (#3 below), identify the existing product to reactivate (in #4-12 below), and proceed to Section X – Updates to Labeling, Advertising, Consumer Information (Material File))

☐ **Updating existing tobacco product's establishment association**
(Provide the effective date of change (#3 below), identify the existing product to update (in #4 –12 below), and provide updated establishment association in Part B, then proceed to Section X – Updates to Labeling, Advertising, Consumer Information (Material File))

☐ **Adding new tobacco product not previously listed which was introduced into commercial distribution**
(Provide the effective date of change (#3 below) and provide new product information in Part E-H)

3. Effective Date of Change *(mm/dd/yyyy)** _____

Select the applicable statement for the effective date of change provided above:

☐ New tobacco product added, provided date introduced into commercial distribution

☐ Previously listed tobacco product inactivated, provided date removed from commercial distribution

☐ Previously listed tobacco product reactivated, provided the date the product was re-introduced into commercial distribution

Identification of Existing Tobacco Product to Update, Inactivate, or Reactivate

4. Tobacco Product Name (including brand and subbrand)	5. Date Introduced into Commercial Distribution (*mm/dd/yyyy*)
6. Tobacco Product Category	7. Tobacco Product Subcategory
8. TP #	9. Universal Product Code (UPC)

10. Alternative Industry Product Identification Number and Type (if no UPC)

11. Date Re-introduced into Commercial Distribution (*mm/dd/yyyy) (if applicable)*	12. Date Removed from Commercial Distribution (*mm/dd/yyyy) (if applicable)*

Part A – Updates to Existing Tobacco Product Identification

Instructions for Part A – Updates to Existing Tobacco Product Identification

Use macro-enabled Form FDA 3741b product list spreadsheet as a guide for the applicable attributes and selectable options based on product category and subcategory for fields entered below. Provide updated values for fields that changed since last submission. Leave blank any field that did not change.

A.1 – Updates to Existing Tobacco Product Identifiers

1. Product Name (including brand and subbrand)

2. TP # (*if updating previously listed product)*

3. Does product have a Universal Product Code (UPC)? *(select one)**

☐ Yes, provide UPC: _____

☐ No, select if product does not have a UPC *(must provide an Alternative Industry Product Identification Number below)*

4. Alternative Industry Product Identification Number (if no UPC)	5. Alternative Industry Product Identification Number Type *(select one)*
	☐ SKU (Stock Keeping Unit) ☐ Catalog or Item # ☐ EAN (International Article Number) ☐ GTIN (Global Trade Item Number) ☐ Other *(Specify)*

6. Product Category and Subcategory

☐ **Cigarettes**

- Filtered Cigarettes
- Non-Filtered Cigarettes
- Cigarettes – Other *(Specify)*

☐ **Cigars**

- Cigar Component
- Cigar Tobacco Filler
- Filtered, Sheet-Wrapped Cigars
- Unfiltered, Leaf-Wrapped Cigars
- Unfiltered, Sheet-Wrapped Cigars
- Cigars – Other *(Specify)*

☐ **Oral Nicotine Products**

- Nicotine Pouch
- Oral Nicotine – Other *(Specify)*

☐ **Roll-Your-Own (RYO) Tobacco Products**

- RYO Filter
- RYO Filtered Cigarette Tube
- RYO Non-Filtered Cigarette Tube
- RYO Paper Tip
- RYO Tobacco Filler
- RYO Rolling Paper
- RYO – Other *(Specify)*

☐ **Electronic Nicotine Delivery Systems (ENDS)/(Vapes)**

- Closed E-Cigarette
- Closed E-Liquid
- ENDS Component
- Open E-Cigarette
- Open E-Liquid
- ENDS – Other *(Specify)*

☐ **Heated Tobacco Products (HTP)**

- Closed HTP
- Open HTP
- HTP Consumable
- HTP Component
- HTP – Other *(Specify)*

☐ **Pipe Tobacco Products**

- Pipe
- Pipe Component
- Pipe Tobacco Filler
- Pipe – Other *(Specify)*

☐ **Smokeless Tobacco Products**

- Dissolvable
- Loose Chewing Tobacco
- Loose Dry Snuff
- Loose Moist Snuff
- Loose Snus
- Portioned Chewing Tobacco
- Portioned Moist Snuff
- Portioned Snus
- Smokeless – Other *(Specify)*

☐ **Waterpipe Tobacco Products**

- Waterpipe
- Waterpipe Component
- Waterpipe Heat Source
- Waterpipe Tobacco Filler
- Waterpipe – Other *(Specify)*

☐ **Other Products**

- Other Products – Other *(Specify)*

7. Tobacco Product Type *(select one)*

☐ Finished Tobacco Product ☐ Consumer Use Bulk Tobacco Product ☐ For Further Manufacturing (FFM)

A.2 – Updates to Existing Tobacco Product Attributes/Properties

1. Package Type

Tobacco Product Quantity
(at least one of the below must be provided to quantitate the product as appropriate per product category/subcategory)

2. Product Quantity *(Numeric value and units)*	3. Product Quantity Mass *(Numeric value and units)*
4. Portion Count *(Numeric value and units)*	5. Portion Mass *(Numeric value and units)*

Tobacco Product Flavor

6. Characterizing Flavor *(select one)*

☐ Menthol ☐ Tobacco ☐ Unflavored ☐ Flavored *(specify below)*

7. Flavor Name *(if flavored)*	8. Flavor Description *(if flavored)*

Tobacco Product Nicotine Attributes

9. Nicotine Concentration *(Numeric value)*	10. Nicotine Concentration *(Units) (select one)*
	☐ mg/ml ☐ %W/W ☐ mg/unit *(specify unit)* _____ ☐ None

11. Nicotine Source *(select one)*

☐ Tobacco Derived Nicotine (TDN) ☐Non-Tobacco Derived Nicotine (NTN) ☐ Both ☐ None

E-Liquid Concentration (if applicable)

12. PG *(Numeric value)*	13. VG *(Numeric value)*	14. E-Liquid Volume *(Numeric value and units)*

Device/Battery Information (if applicable)

15. Wattage *(Numeric value and units)*	16. Battery Capacity *(Numeric value and units)*

Length (if applicable)

17. Length Description

☐ King ☐ Long ☐ XL ☐ Queen ☐ None ☐ Other *(specify)*

18. Length *(Numeric value and units)*

Width (if applicable)

19. Width *(Numeric value and units)*

Diameter (if applicable)

20. Diameter Description	21. Diameter Format	22. Diameter *(Numeric value and units)*

Height (if applicable)

23. Height *(Numeric value and units)*

Portion Thickness (if applicable)

24. Portion Thickness *(Numeric value and units)*

Other (if applicable)

25. Tobacco Cut Style	26. Filter Ventilation *(Percentage)*	27. Number of Hoses

28. Source of Energy	29. Wrapper Material

30. Tip Type	31. Additional Properties

Part B – Updates to Existing Tobacco Product – Establishment Associations and Manufacturing and Commercial Distribution Status

Instructions for Part B – Updates to Tobacco Product – Establishment Associations and Manufacturing and Commercial Distribution Status

For each product listed, indicate which registered establishment is responsible for manufacturing the product, when the product was first introduced for commercial distribution, and the commercial distribution destination of the product. Please note, while a product can be manufactured and distributed for both domestic and foreign distribution, due to differing requirements that product must appear as two separate line items (i.e., two separate products) based on the difference in commercial distribution destination. Provide updated values for fields that changed since last submission. Leave blank any field that did not change.

B.1 – Updates to Associated Manufacturing Establishment Information and Manufacturing and Commercial Distribution Status

Instructions for Part B.1 – Updates to Associated Manufacturing Establishment Information and Manufacturing and Commercial Distribution Status

Submit additional sheets for each additional establishment that needs to be associated to the product identified above.

Updates to Associated Establishment Identification

1. Establishment Legal Name	2. Does the establishment do business by any other name? ☐ Yes *(continue to IX.B.1 #3)* ☐ No *(skip to IX.B.1 #4)*	3. Establishment DBA Name(s) *(if applicable)*

4. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Establishment D&B DUNS® Number *(if applicable)*

Updates to Associated Establishment Physical Address

6. Street Address Line 1		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

Updates to Manufacturing and Commercial Distribution Status

12. Date Tobacco Product Introduced for Commercial Distribution *(mm/dd/yyyy)*

13. Commercial Distribution Destination *(select one)*	14. Country of Origin *(select one)*
☐ Domestic Market *(U.S.)*	☐ Domestic Establishment *(U.S.)*
☐ Foreign Market *(for Export From U.S.)*	☐ Foreign Establishment

B.2 – Updates to Other Businesses (not required to register and list) that are associated with this product

1. Other Associated Business is: *(select one)*

☐ Brand Owner ☐ Importer ☐ Consignee ☐ Retailer ☐ Distributor ☐ Wholesaler

☐ Other *(Specify)*

Updates to Identification of the Other Associated Businesses (not required to register and list)

2. Business Legal Name	3. Does business go by any other name? ☐ Yes *(continue to IX.B.2 #4)* ☐ No *(skip to IX.B.2 #5)*	4. Business DBA Name(s) *(if applicable)*

5. Business Website

Updates to Associated Business Physical Address

6. Street Address Line 1		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

Part C – Updates to Product Standards and Information for Tobacco Products for Export

Instructions for Part C – Updates to Product Standards and Information for Tobacco Products for Export

For each product listed, indicate if there are any applicable product standards under FD&C Act section 907 and identify the product standard. For each product for export (i.e., product with a country of origin in the U.S. and commercial distribution destination of "foreign export") please confirm whether or not the exported product conforms to applicable product standards per section 907 of the FD&C Act. Report the destination country and quantity of non-conforming tobacco products intended for exported to the indicated destination country. Section IX, Part C #2-4 can be left blank for all products whose country of origin is the U.S. and commercial distribution destination is domestic.

Updates to Tobacco Product Standards and Information for Tobacco Products for Export

1. Have there been any changes in applicable product standard information since last submission *(select one)*

☐ Yes *(continue below to provide information. Leave blank any field that did not change)*

☐ No *(skip to Updates to Tobacco Products for Export)*

2. Is your tobacco product subject to any tobacco product standards under Section 907 of the FD&C Act? *(select one)*

☐ Yes *(provide applicable tobacco product standards and continue below)*

☐ No *(provide reason tobacco product standards do not apply to this product and then proceed to Section IX, Part D)*

Updates to Tobacco Products for Export

3. Have there been any changes in applicable product standard information since last submission *(select one)*

☐ Yes *(continue below to provide information. Leave blank any field that did not change)*

☐ No *(proceed to Section IX.D – Updates to Tobacco Product Marketing Authorization Status and Information)*

*For domestic tobacco products intended for export which **do not conform** to applicable tobacco product standards (leave blank if commercial distribution destination is the U.S.).*

4. Does your exported tobacco product conform to applicable tobacco product standards per Section 907 of the FD&C Act? *(select one)*

☐ Yes *(proceed to Section IX, Part D)*

☐ No *(continue below)*

5. Specify the manner in which the exported tobacco product does not conform to applicable tobacco product standards.

6. Which destination country(ies) were these tobacco products exported to in the previous calendar year?
(Provide the quantity of tobacco product shipped to each country of destination during the previous calendar year.)

Destination Country	Quantity of Non-Conforming Tobacco Product Exported

Part D – Updates to Tobacco Product Marketing Authorization Status and Information

Instructions for Part D – Updates to Tobacco Product Marketing Authorization Status and Information

In the sections below, please indicate whether the listed tobacco product has an associated STN for a premarket tobacco product application (PMTA), substantial equivalence (SE) report, exemption from substantial equivalence request (EX REQ), pre-existing (PX) product review, or modified risk tobacco product application (MRTPA). See FDA's website for additional information on marketing authorization pathways and pre-existing products: https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product

Updates to Tobacco Product Marketing Authorization Status and Information

1. Have there been any changes to the marketing authorization status or information since last submission *(select one)*

☐ Yes *(continue below to provide information. Leave blank any field that did not change)*

☐ No *(proceed to Section IX.E – Identification of New Tobacco Product Information to Add to Product List (if applicable) or proceed to Section X)*

2. Tobacco product is *(select all that apply)*

☐ A new tobacco product (not commercially marketed in the U.S. as of February 15, 2007)

☐ A pre-existing tobacco product (commercially marketed in the U.S. as of February 15, 2007)

☐ A modified risk tobacco product

☐ A new tobacco product that is substantially equivalent to a predicate tobacco product that was commercially marketed in the U.S. as of February 15, 2007

☐ A provisional SE tobacco product marketed after February 15, 2007, but before March 11, 2011

☐ Has a SE exemption request

3. Date product was first marketed in the U.S. *(mm/dd/yyyy)*

4. Has a PMTA, MRTPA, SE report, or SE exemption request been submitted for the listed tobacco product, or has the listed product been submitted for Voluntary PX review? *(select one)*

☐ Yes *(continue below)*

☐ No *(proceed to Section X)*

5. What marketing authorization pathways has the listed product been submitted for? *(select all that apply and provide associated STNs and date of submission)*

☐ PMTA

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., PM0000000.PD1)* ☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	Date Submitted *(mm/dd/yyyy)*

☐ MRTPA

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., MR0000000.PD1)* ☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	Date Submitted *(mm/dd/yyyy)*

☐ SE Report

Associated STNs* *(provide accompanying PD #s, if applicable)* (e.g., SE0000000.PD1)* ☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	Date Submitted *(mm/dd/yyyy)*

☐ SE exemption request (EX REQ)

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., EX0000000.PD1)* ☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	Date Submitted *(mm/dd/yyyy)*

☐ Voluntary pre-existing tobacco product review

Associated STNs *(provide accompanying PD #s, if applicable) (e.g., PX0000000)* ☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	Date Submitted *(mm/dd/yyyy)*

6. Current marketing authorization status of product *(select all that apply)*

☐ Marketing Granted Order (MGO)
☐ Marketing Denial Order (MDO)
☐ Modified Risk Order
☐ Modified Risk Denial Order
☐ Substantial Equivalence Order (SE order)
☐ Not Substantially Equivalent Order (NSE order)
☐ SE Exempt Order
☐ SE Not Exempt Order
☐ Pre-Existing Tobacco Product Status Determination
☐ Unable to Determine Pre-Existing Tobacco Product
☐ Other *(Specify)*

7. Submitter Name	8. Applicant Name
9. Product Name as Appeared on Submission	10. Date Notified of Most Recent Status by FDA *(mm/dd/yyyy)*
11. Predicate Tobacco Product *(if applicable)*	12. Modification *(if applicable)*

13. Modified Risk Statement(s) and Representation(s) *(if applicable)*

Part E – Identification of New Tobacco Product Information to Add to Product List

Instructions for Part E – Identification of New Tobacco Product Information to Add to Product List

Use Form FDA 3741b to provide the unique product identifiers and attributes for each product. If you are submitting electronically, you may complete Part E for each product to be listed instead of Form FDA 3741b. Use additional sheets as needed for each additional product.

E.1 – New Tobacco Product Identifiers

1. Product Name (including brand and subbrand)*

2. Does product have a Universal Product Code (UPC)? *(select one)**

☐ Yes, provide UPC: _____
☐ No, select if product does not have a UPC *(must provide an Alternative Industry Product Identification Number below)*

3. Alternative Industry Product Identification Number (if no UPC)	4. Alternative Industry Product Identification Number Type *(select one)* ☐ SKU (Stock Keeping Unit) ☐ Catalog or Item # ☐ EAN (International Article Number) ☐ GTIN (Global Trade Item Number) ☐ Other *(Specify)*

5. Product Category and Subcategory*

☐ **Cigarettes**

- Filtered Cigarettes
- Non-Filtered Cigarettes
- Cigarettes – Other *(Specify)*

☐ **Cigars**

- Cigar Component
- Cigar Tobacco Filler
- Filtered, Sheet-Wrapped Cigars
- Unfiltered, Leaf-Wrapped Cigars
- Unfiltered, Sheet-Wrapped Cigars
- Cigars – Other *(Specify)*

☐ **Electronic Nicotine Delivery Systems (ENDS)/(Vapes)**

- Closed E-Cigarette
- Closed E-Liquid
- ENDS Component
- Open E-Cigarette
- Open E-Liquid
- ENDS – Other *(Specify)*

☐ **Oral Nicotine Products**

- Nicotine Pouch
- Oral Nicotine – Other *(Specify)*

☐ **Roll-Your-Own (RYO) Tobacco Products**

- RYO Filter
- RYO Filtered Cigarette Tube
- RYO Non-Filtered Cigarette Tube
- RYO Paper Tip
- RYO Tobacco Filler
- RYO Rolling Paper
- RYO – Other *(Specify)*

☐ **Smokeless Tobacco Products**

- Dissolvable
- Loose Chewing Tobacco
- Loose Dry Snuff
- Loose Moist Snuff
- Loose Snus
- Portioned Chewing Tobacco
- Portioned Moist Snuff
- Portioned Snus
- Smokeless – Other *(Specify)*

☐ **Heated Tobacco Products (HTP)**

- Closed HTP
- Open HTP
- HTP Consumable
- HTP Component
- HTP – Other *(Specify)*

☐ **Pipe Tobacco Products**

- Pipe
- Pipe Component
- Pipe Tobacco Filler
- Pipe – Other *(Specify)*

☐ **Waterpipe Tobacco Products**

- Waterpipe
- Waterpipe Component
- Waterpipe Heat Source
- Waterpipe Tobacco Filler
- Waterpipe – Other *(Specify)*

☐ **Other Products**

- Other Products – Other *(Specify)*

6. Tobacco Product Type *(select one)**

☐ Finished Tobacco Product ☐ Consumer Use Bulk Tobacco Product ☐ For Further Manufacturing (FFM)

E.2 – New Tobacco Product Attributes/Properties

1. Package Type*

Tobacco Product Quantity*
(at least one of the below must be provided to quantitate the product as appropriate per product category/subcategory)

2. Product Quantity *(Numeric value and units)*	3. Product Quantity Mass *(Numeric value and units)*
4. Portion Count *(Numeric value and units)*	5. Portion Mass *(Numeric value and units)*

Tobacco Product Flavor

6. Characterizing Flavor *(select one)**

☐ Menthol ☐ Tobacco ☐ Unflavored ☐ Flavored *(specify below)*

7. Flavor Name *(if flavored)*	8. Flavor Description *(if flavored)*

Tobacco Product Nicotine Attributes

9. Nicotine Concentration *(Numeric value)*	10. Nicotine Concentration *(Units) (select one)*
	☐ mg/ml ☐ %W/W ☐ mg/unit *(specify unit)* _____ ☐ None

11. Nicotine Source *(select one)**

☐ Tobacco Derived Nicotine (TDN) ☐ Non-Tobacco Derived Nicotine (NTN) ☐ Both ☐ None

E-Liquid Concentration (if applicable)

12. PG *(Numeric value)*	13. VG *(Numeric value)*	14. E-Liquid Volume *(Numeric value and units)*

Device/Battery Information (if applicable)

15. Wattage *(Numeric value and units)*	16. Battery Capacity *(Numeric value and units)*

Length (if applicable)

17. Length Description

☐ King ☐ Long ☐ XL ☐ Queen ☐ None ☐ Other *(specify)*

18. Length *(Numeric value and units)*

Width (if applicable)

19. Width *(Numeric value and units)*

Diameter (if applicable)

20. Diameter Description	21. Diameter Format	22. Diameter *(Numeric value and units)*

Height (if applicable)

23. Height *(Numeric value and units)*

Portion Thickness (if applicable)

24. Portion Thickness *(Numeric value and units)*

Other (if applicable)

25. Tobacco Cut Style	26. Filter Ventilation *(Percentage)*	27. Number of Hoses

28. Source of Energy	29. Wrapper Material

30. Tip Type	31. Additional Properties

Part F – New Tobacco Product – Establishment Associations and Manufacturing and Commercial Distribution Status

Instructions for Part F – New Tobacco Product – Establishment Associations and Manufacturing and Commercial Distribution Status

For each new tobacco product listed, indicate which registered establishment is responsible for manufacturing the product, when the product was first introduced for commercial distribution, and the commercial distribution destination of the product. Please note, while a product can be manufactured and distributed for both domestic and foreign distribution, due to differing requirements that product must appear as two separate products based on the difference in commercial distribution destination.

F.1 – Associated Manufacturing Establishment Information and Manufacturing and Commercial Distribution Status for New Product

Instructions for Part F.1 – Associated Manufacturing Establishment Information and Manufacturing and Commercial Distribution Status for New Product

Submit additional sheets for each additional establishment that needs to be associated to the product identified above.

Associated Establishment Identification for New Product

1. Establishment Legal Name*	2. Does the establishment do business by any other name?* ☐ Yes *(continue to IX.F.1 #3)* ☐ No *(skip to IX.F.1 #4)*	3. Establishment DBA Name(s) *(if applicable)*

4. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	5. Establishment D&B DUNS® Number *(if applicable)*

Associated Establishment Physical Address

6. Street Address Line 1*	7. Street Address Line 2 *(Apartment, Suite, Building Number)*

8. City*	9. State, Province, or Territory*	10. Country*	11. ZIP or Postal Code*

Manufacturing and Commercial Distribution Status for New Product

12. Date Tobacco Product Introduced for Commercial Distribution* *(mm/dd/yyyy)*

13. Commercial Distribution Destination of Establishment's Products *(select one)** ☐ Domestic Market *(U.S.)* ☐ Foreign Market *(for Export From the U.S.)*	14. Country of Origin *(select one)** ☐ Domestic Establishment *(U.S.)* ☐ Foreign Establishment

F.2 – Other Businesses (Not Required to Register and List) That Are Associated With This New Tobacco Product

1. Other Associated Business is: *(select one)*

☐ Brand Owner ☐ Importer ☐ Consignee ☐ Retailer ☐ Distributor ☐ Wholesaler

☐ Other *(Specify)*

Identification of the Other Associated Businesses (Not Required to Register and List)

2. Business Legal Name	3. Does business go by any other name? ☐ Yes *(continue to IX.F.2 #4)* ☐ No *(skip to IX.F.2 #5)*	4. Business DBA Name(s) *(if applicable)*

5. Business Website

Associated Business Physical Address			
6. Street Address Line 1		7. Street Address Line 2 *(Apartment, Suite, Building Number)*	
8. City	9. State, Province, or Territory	10. Country	11. ZIP or Postal Code

Part G – Product Standards and Information for New Tobacco Products for Export

Instructions for Part G – Product Standards and Information for New Tobacco Products for Export

For each product listed, indicate if there are any applicable product standards under FD&C Act section 907 and identify the product standard. For each product for export (i.e., product with a country of origin in the U.S. and commercial distribution destination of "foreign export") please confirm whether or not the exported product conforms to applicable product standards per section 907 of the FD&C Act. Report the destination country and quantity of non-conforming tobacco products intended for exported to the indicated destination country. Section IX.G #2-4 can be left blank for all products whose country of origin is the U.S. and commercial distribution destination is domestic.

Tobacco Product Standards and Information for New Tobacco Products for Export

1. Is your tobacco product subject to any tobacco product standards under Section 907 of the FD&C Act? *(select one)**

☐ Yes *(provide applicable tobacco product standards and continue below)*

☐ No *(provide reason tobacco product standards do not apply to this product and then proceed to Section IX, Part H)*

New Tobacco Products for Export

For domestic tobacco products intended for export that are subject to an applicable tobacco product standard (proceed to IX.H #3 if commercial distribution destination is the U.S.).

2. Does your exported tobacco product conform to applicable tobacco product standards per Section 907 of the FD&C Act? *(select one)**

☐ Yes *(proceed to Section IX, Part H)*

☐ No *(continue below)*

3. Specify the manner in which the exported tobacco product does not conform to applicable tobacco product standards.*

4. Which destination country(ies) were these tobacco products exported to in the previous calendar year?*
(Provide the quantity of tobacco product shipped to each country of destination during the previous calendar year.)

Destination Country	Quantity of Non-Conforming Tobacco Product Exported

Part H – New Tobacco Product Marketing Authorization Status and Information

Instructions for Part H – New Tobacco Product Marketing Authorization Status and Information

In the sections below, please indicate whether the newly listed tobacco product has an associated STN for a premarket tobacco product application (PMTA), substantial equivalence (SE) report, exemption from substantial equivalence request (EX REQ), pre-existing (PX) product review, or modified risk tobacco product application (MRTPA). See FDA's website for additional information on marketing authorization pathways and pre-existing products: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders.

New Tobacco Product Marketing Authorization Status and Information

1. Tobacco product is *(select all that apply)**

- ☐ A new tobacco product (not commercially marketed in the U.S. as of February 15, 2007)
- ☐ A pre-existing tobacco product (commercially marketed in the U.S. as of February 15, 2007)
- ☐ A modified risk tobacco product
- ☐ A new tobacco product that is substantially equivalent to a predicate tobacco product that was commercially marketed in the U.S. as of February 15, 2007
- ☐ A provisional SE tobacco product marketed after February 15, 2007, but before March 11, 2011
- ☐ Has a SE exemption request

2. Date product was first marketed in the U.S *(mm/dd/yyyy)*

3. Has a PMTA, MRTPA, SE report, or SE exemption request been submitted for the tobacco product being listed, or has the product been submitted for Voluntary PX review? *(select one)**

- ☐ Yes *(continue below)*
- ☐ No *(proceed to Section X)*

4. What marketing authorization pathways has the listed product been submitted for?
(select all that apply and provide associated STNs and date of submission)

☐ PMTA

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., PM0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ MRTPA

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., MR0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ SE Report

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., SE0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ SE exemption request (EX REQ)

Associated STNs *(provide accompanying PD #s, if applicable)* (e.g., EX0000000.PD1)*	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

☐ Voluntary pre-existing tobacco product review

Associated STNs *(provide accompanying PD #s, if applicable) (e.g., PX0000000)**	Date Submitted *(mm/dd/yyyy)*
☐ Select if FDA has not yet acknowledged receipt of submission and assigned a STN	

5. Current marketing authorization status of product *(select all that apply)*

☐ Marketing Granted Order (MGO)
☐ Marketing Denial Order (MDO)
☐ Modified Risk Order
☐ Modified Risk Denial Order
☐ Substantial Equivalence Order (SE order)
☐ Not Substantially Equivalent Order (NSE order)
☐ SE Exempt Order
☐ SE Not Exempt Order
☐ Pre-Existing Tobacco Product Status Determination
☐ Unable to Determine Pre-Existing Tobacco Product
☐ Other *(Specify)*

6. Submitter Name	7. Applicant Name
8. Product Name as Appeared on Submission	9. Date Notified of Most Recent Status by FDA *(mm/dd/yyyy)*
10. Predicate Tobacco Product *(if applicable)*	11. Modification *(if applicable)*

12. Modified Risk Statement(s) and Representation(s) *(if applicable)*

SECTION X – UPDATES TO LABELING, ADVERTISING, CONSUMER INFORMATION (MATERIAL FILE(S))

Instructions for Section X – Updates to Labeling, Advertising, Consumer Information (Material File(s))

Confirm whether there have been any changes to the labeling, consumer information, and advertising (material file) information since last submission, indicate the type of change (e.g., adding new material file, updating existing material file information, updating product-material file association etc.), identify each material file impacted by the change, and provide the updated new values for the impacted fields. Leave the field blank if there have been no updates to report since the last submission. Submit additional copies of this section for each additional labeling, advertising, and/or consumer information (material file) that a change needs to be reported for.

If new material file(s) need to be added, provide the same information required for initial material file submissions per Section VI and provide sufficient product identifiers to identify the product(s) that need to be associated to the new material file.

If updating a previously submitted material file, identify the material file to update (i.e., material file name, material file category and type).

1. Have there been any changes to the labeling, advertising, or consumer information (material file(s)) since the last submission? *(select one)**

☐ Yes *(continue below to provide information on the material file changes)*
☐ No *(proceed to Section XI – Certification Statement)*

2. Select the appropriate summary of the change needed *(select all that apply)*

☐ **Updating existing material file information for previously listed tobacco product**
(Identify the material file to update in Section X #4-9 and provide updated values for the fields that changed in Section X.A #2-11)

☐ **Removing existing material file for listed tobacco product**
(Identify the material file that needs to be removed in Section X #4-9 and add a new material file if needed in Section X.B.1 - B.2)

☐ **Replacing material file for previously listed tobacco product**
(Identify the material file that needs to be replaced in Section X #4-9 and provide information on the new replacement material file in Section X.B.1-B.2)

☐ **Updating product-material file association**
(Identify the material file and current associated product in Section X # 4-13 and provide, then identify what other product(s) the material file needs to be associated with in Section X.A.2)

☐ **Adding new material file to previously listed tobacco product**
(Identify the previously listed tobacco product in Section X #10-13 and provide information on the new material file to associated to it in Section X.A.1)

☐ **Adding new material file to a new tobacco product**
(Identify the newly added product in Section X.A and provide information on the new material file in Section X.B.1)

3. Effective Date of Change, select the applicable statement below:*

☐ Material file was removed, provide date last disseminated (*mm/dd/yyyy)* _____

☐ Material file was replaced, provide date last disseminated (*mm/dd/yyyy)* for the previous version _____
and date first disseminated (*mm/dd/yyyy)* for the replacement (i.e., new version) _____

☐ Material file was added, provide date first disseminated (*mm/dd/yyyy)* _____

Identification of Existing Labeling, Advertising, Consumer Information (Material File) to Update, Replace, or Remove

4. Material file identified below needs to be *(select one)* ☐ Updated ☐ Removed ☐ Replaced	5. Material File Name
6. Material File Type	7. Material File Category
8. Date First Disseminated (*mm/dd/yyyy)*	9. Date Last Disseminated (*mm/dd/yyyy) (if applicable)*

Identification of Existing Listed Tobacco Product Material File is Associated With

10. Associated Product Name(s) (including brand and subbrand name)	11. Associated Product TP #s
12. Associated Product UPCs	13. Alternative Industry Product Identification Number and Type (if no UPC)

Part A – Updates to Labeling, Advertising, Consumer Information (Material File)

A.1 – Updates to Labeling, Advertising, Consumer Information (Material File)

1. Have there been any changes to the existing labeling, advertising, consumer information for the material file identified above since last submission? *(select one)*

☐ Yes *(Provide updated values for fields that changed below. Leave blank any field that did not change)*

☐ No *(skip to Section X.A.2 – Updates to Tobacco Product - Labeling, Advertising, Consumer Information (Material File) Associations)*

2. Material File Name

3. Date First Disseminated *(mm/dd/yyyy)*	4. Date Last Disseminated *(mm/dd/yyyy) (if applicable)*

5. Material Contains *(select all that apply)*

☐ Labeling ☐ Advertising ☐ Consumer Information

Note: *The submitter's designation of the material being submitted as labeling, advertising, or consumer information does not necessarily reflect FDA's interpretation or designation.*

6. Select the type of labeling/advertising/consumer information from the options below that best describes the type of material *(select all that apply)*

☐ Affixed Tag	☐ Email	☐ Pamphlet	☐ Social Media
☐ Brochure	☐ Flyer or Handout	☐ Point of Sale	☐ Text Messaging
☐ Business Card	☐ Instructions	☐ Press Release	☐ Trade Show Material
☐ Carton	☐ Large Sign	☐ Package Label	☐ Website or Banner
☐ Catalog	☐ Magazine, Periodical, or Print	☐ Reviews or Feedback	☐ Wrapper
☐ Cautions or Warnings		☐ Rewards or Loyalty Cards	☐ Other *(Specify)*
☐ Cigar Box	☐ Mobile App		
☐ Coupons	☐ Outer Container	☐ Shipping and Packaging	
☐ Digital Information	☐ Package Inserts	☐ Small Sign	
☐ Direct Mailer	☐ Package Onserts		

7. Official Product Website Address(es) or URL(s)

8. Location of Label on finished product packaging *(select one)*

☐ Top ☐ Front ☐ Side ☐ Back ☐ Bottom ☐ Other *(Specify)*

9. Will there be a submission of a package label plan?

☐ Yes ☐ No

10. What variables are captured in the product variation index?

11. Additional Material File Properties *(if applicable)*

A.2 – Updates to Tobacco Product - Labeling, Advertising, Consumer Information (Material File) Associations

1. Have there been any changes to the material file-product association(s) for the material file identified above since last submission? *(select one)*

☐ Yes *(continue below to provide information on the changes. Leave fields blank if they did not change)*

☐ No *(proceed to Section X.B – New Labeling, Advertising, Consumer Information (Material File) to Add)*

2. Tobacco Product Name (including brand and subbrand)	3. Universal Product Code (UPC)

4. Alternative Industry Product Identification Number (if no UPC)	5. Alternative Industry Product Identification Number Type *(select one)* ☐ SKU (Stock Keeping Unit) ☐ Catalog or Item # ☐ EAN (International Article Number) ☐ GTIN (Global Trade Item Number) ☐ Other *(Specify)*

6. Tobacco Product Category	7. Tobacco Product Subcategory

8.Tobacco Product Type

☐ Finished Tobacco Products ☐ Consumer Use Bulk Tobacco Products ☐ For Further Manufacturing (FFM)

Part B – New Labeling, Advertising, Consumer Information (Material File) to Add

B.1 – Identification of New Labeling, Advertising, Consumer Information (Material File) to Add

1. Material File Name*	2. Date First Disseminated *(mm/dd/yyyy)**

3. Material Contains *(select all that apply)**

☐ Labeling ☐ Advertising ☐ Consumer Information

Note: *The submitter's designation of the material being submitted as labeling, advertising, or consumer information does not necessarily reflect FDA's interpretation or designation.*

4. Select the type of labeling/advertising/consumer information from the options below that best describes the type of material *(select all that apply)*

☐ Affixed Tag	☐ Email	☐ Pamphlet	☐ Social Media
☐ Brochure	☐ Flyer or Handout	☐ Point of Sale	☐ Text Messaging
☐ Business Card	☐ Instructions	☐ Press Release	☐ Trade Show Material
☐ Carton	☐ Large Sign	☐ Package Label	☐ Website or Banner
☐ Catalog	☐ Magazine, Periodical, or Print	☐ Reviews or Feedback	☐ Wrapper
☐ Cautions or Warnings	☐ Mobile App	☐ Rewards or Loyalty Cards	☐ Other *(Specify)*
☐ Cigar Box	☐ Outer Container	☐ Shipping and Packaging	
☐ Coupons	☐ Package Inserts	☐ Small Sign	
☐ Digital Information	☐ Package Onserts		
☐ Direct Mailer			

5. Official Product Website Address(es) or URL(s)

6. Location of Label on finished product packaging *(select one)*

☐ Top ☐ Front ☐ Side ☐ Back ☐ Bottom ☐ Other *(Specify)*

7. Will there be a submission of a package label plan?

☐ Yes ☐ No

8. What variables are captured in the product variation index?

9. Additional Material File Properties *(if applicable)*

B.2 – Associated Tobacco Products for New Labeling, Advertising, Consumer Information (Material File)

☐ Select if new material file is being associated to existing product identified in X.A. *(then, proceed to Section XI)*

1. Tobacco Product Name (including brand and subbrand)*	2. Universal Product Code (UPC)*

3. Alternative Industry Product Identification Number (if no UPC)	4. Alternative Industry Product Identification Number Type *(select one)*
	☐ SKU (Stock Keeping Unit) ☐ Catalog or Item # ☐ EAN (International Article Number) ☐ GTIN (Global Trade Item Number) ☐ Other *(Specify)*

5. Tobacco Product Category	6. Tobacco Product Subcategory

SECTION XI – CERTIFICATION STATEMENT

Certification Statement

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to update and report changes to this information as required under section 905 of the Federal Food, Drug, and Cosmetic (FD&C) Act. 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 registrant'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.

☐ **Agree***

Identity of the Signatory *(select all that apply)**:

☐ Owner (listed in Section IV, Part B)

☐ Operator (listed in Section IV, Part C)

☐ Authorized Representative of Owner (listed in Section III, Part A)

☐ Authorized Representative of Operator (listed in Section III, Part A)

1. Signature*	2. Date *(mm/dd/yyyy)**

3. Typed Name and Title*

Appendix A: Terminology

In this form, FDA intends to use the following terminology in implementing the registration and product listing requirements of section 905 of the FD&C Act.

1. **Accessory:** means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco or nicotine, and is not made or derived from tobacco or nicotine from any source; and meets either of the following: (1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored tobacco product; or (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.
2. **Brand:** means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.
3. **Brand owner:** means a person that owns a brand, through creation, acquisition, trademark, patent, copyright, or otherwise, and has directly or through license the control and/or direction of the brand.
4. **Bulk tobacco product:** means a tobacco product not sealed in final packaging but otherwise suitable for consumer use as a tobacco product.
5. **Commercial distribution:** means any distribution of a tobacco product, whether domestic or imported, to consumers or to another person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. “Commercial distribution” does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term “commercial distribution” has the same meaning, except that it does not include distribution of a tobacco product that is neither imported nor offered for import into the United States. Nor does it include shipment of a tobacco product into a foreign trade zone if the product is then exported and not further distributed in the United States.
6. **Component or part:** means any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.
7. **Consignee:** means the person in the United States who, at the time of U.S. entry of the tobacco product offered for importation, either owns the tobacco product, has purchased the tobacco product, has agreed in writing to purchase the tobacco product, or is the person named in a bill of lading to whom or to whose order the bill promises delivery. “Consignee” does not include individual purchasers of tobacco products for personal consumption.
8. **Direct Account(s):** means all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the tobacco product manufacturer or from any person under control of the manufacturer. “Direct Account(s)” may include wholesalers, distributors, and retailers. “Direct Account(s)” do not include individual purchasers of tobacco products for personal consumption.
9. **Domestic establishment:** means an establishment in any State or Territory or possession of the United States.
10. **Electronic Nicotine Delivery System (ENDS):** means an electronic nicotine delivery system that delivers aerosolized e-liquid when inhaled. ENDS products fall within the definition of “tobacco product” under section 201(rr) of the FD&C Act and are subject to the tobacco product authorities in chapter IX of the FD&C Act. Components and parts of ENDS products sold separately (e.g., e-liquids) are also subject to FDA’s tobacco products authorities.
11. **Establishment:** means a place of business, under one ownership at one general physical location, engaged in an operation described in § 1108.20(a). A single building may house more than one distinct establishment if the establishments are under separate ownership. Establishment refers to both domestic and foreign establishments unless otherwise noted.
12. **Finished tobacco product:** means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).
13. **Foreign establishment:** means an establishment other than a domestic establishment.
14. **Importer**: means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States. “Importer” would not include individual purchasers of tobacco products for personal consumption.

15. **Industry product identification number:** means a unique, product-specific identifier or alphanumeric code, such as a universal product code (UPC), stock keeping unit (SKU), item # or catalog #, that industry generates for internal record keeping and tracking. FDA intends to utilize an industry product identification number when corresponding with industry as a point of reference to help distinguish a specific product from other similar products made by the same manufacturer but with slight differences in product attributes (such as volume or quantity or packaging).
16. **Labeling:** means all labels and other written, printed, or graphic matter (a) upon any tobacco product or any of its containers or wrappers, or (b) accompanying such tobacco product.
17. **Manufacturer:** means any person who manufactures, prepares, compounds, or processes a tobacco product, including repackaging or relabeling of any tobacco product. Examples of manufacturing include assembling, processing, homogenizing, mixing, formulating, labeling, or packaging. Manufacturers include specification developers, third-party manufacturers, bulk tobacco product manufacturers, and repackagers/relabelers.
18. **Material change:** includes: (a) any change in the tobacco product name (including brand or subbrand), warnings, or instructions for use; (b) any change in the owner or operator, or establishment; (c) any other significant change with respect to consumer information, to other labeling, or to the advertisements for the tobacco product, such as changes to the logo(s), identifiable patterns of color, or product descriptors; (d) any change in the marketing authorization or status for the marketing of such product; or (e) any change with respect to whether or not the product is subject to a tobacco product standard established under section 907 of the FD&C Act (21 U.S.C. 387g). With respect to changes in consumer information or other labeling of the tobacco product, changes that are not significant may include changes to grammar, correction of typographical errors that do not change the content of the labeling, or changes in tax stamp or bar code.
19. **Operator:** means a person, as defined in section 201(e) of the FD&C Act, who has management authority over an establishment.
20. **Owner:** means a person, as defined in section 201(e) of the FD&C Act, who has an ownership interest in an establishment.
21. **Product Identifier Number (PD #):** The number FDA assigns to each product within a submission to distinguish among the products included in that submission. PD #s are only relevant within the context of a specific STN.
22. **Retailer:** Any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.
23. **Representative sampling of advertisements:** means advertising material that gives a comprehensive picture of the promotional claims and campaigns in use for each brand of tobacco product and which includes representative material from each medium being used to promote the product (e.g., advertisements that appear in or on magazines, newspapers, direct mail material, retail or point-of-sale displays, posters, billboards and internet and mobile communications, such as web pages, banner advertisements, and text messages).
24. **Registration ID number (RG ID #):** means the FDA-assigned unique identifier for a registered establishment's registration.
25. **Specification developer:** means a person who controls the design and development of a tobacco product and/or initiates or creates the specifications for the product.
26. **Submission Tracking Number (STN):** The number that FDA assigns to submissions that are received from an applicant, such as a Premarket Tobacco Product Application (PMTA), supplemental PMTA, Substantial Equivalence (SE) report, SE exemption request (EX REQ), Modified Risk Tobacco Product Application (MRTPA), and submission related to investigational tobacco products.
27. **Third-party manufacturer:** means an entity that physically manufactures a tobacco product on behalf of, or to specifications established by, another party, such as a brand owner or specification developer.
28. **Tobacco product:** means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that is a drug under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term "tobacco product" does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.
29. **Tobacco product number (TP #)** refers to a product specific number that is generated by FDA for each product listed on an establishment's registration.

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) by, among other things, adding a new chapter granting the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Under section 201(rr) of the FD&C Act, following amendments by the Consolidated Appropriations Act, 2022 (Public Law 117-103), a tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that is a drug under section 201(g)(1) (21 U.S.C. 321(g)(1)), a device under section 201(h) (21 U.S.C. 321(h)), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). The term "tobacco product" does not mean an article that is a food under section 201(f) (21 U.S.C. 321(f)), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

Generally, to be legally marketed in the United States, the FD&C Act requires "new tobacco products" to have a premarket authorization order in effect. A "new tobacco product" is any tobacco product that was not commercially marketed in the United States as of February 15, 2007, or any modified tobacco product that was commercially marketed after February 15, 2007 (section 910(a) of the FD&C Act). Generally, a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act is required for a new tobacco product unless (1) the manufacturer of the product submitted a report under section 905(j) of the FD&C Act and FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act) or (2) the manufacturer submitted a report under section 905(j)(1)(A)(ii) of the FD&C Act and all modifications are covered by exemptions from the requirements of substantial equivalence granted by FDA under section 905(j)(3) of the FD&C Act.

STATUTORY REQUIREMENTS

Section 905 of the FD&C Act describes the requirements for owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of tobacco product(s) to register these establishments and list their tobacco products with FDA.

- **Section 905(b)** of the FD&C Act requires that "[o]n or before December 31st of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with [FDA] the name, places of business, and all such establishments of that person."
- **Section 905(c)** of the FD&C Act requires that "[e]very person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with [FDA] that person's name, place of business, and such establishment."
- **Section 905(d)** of the FD&C Act requires that "[e]very person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products."
- **Section 905(h)** of the FD&C Act requires that "Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by [FDA]."
- **Section 905(i)(1)** of the FD&C Act requires that all registrants under the subsections above "shall, at the time of registration […] file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying information, such as all consumer information and other labeling.
- **Section 905(i)(3)** of the FD&C Act requires that certain changes in a product list be submitted to FDA biannually, once during June and once during December.

Appendix C: Additional Resources

1. **Family Smoking Prevention and Tobacco Control Act** — Family Smoking Prevention and Tobacco Control Act - An Overview | FDA
2. **FDA Registration and Tobacco Product Listing Guidance for Industry** — Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments | FDA
3. **Tobacco Registration and Product Listing Module Next Generation (TRLM NG) User Guide** — TRLM NG
4. **CTP Guidance Document Search** — Guidance Related to Tobacco Products | FDA
5. **Reference for the Consolidated Appropriations Act, 2022** — Text - H.R.2471 - 117th Congress (2021-2022): Consolidated Appropriations Act, 2022 | Congress.gov | Library of Congress
6. **Manufacturing Compliance** — Manufacturing | FDA
   a. See “Register your establishment and submit list of products, labeling and advertisements” section.