DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

REGISTRATION AND PRODUCT LISTING OF TOBACCO PRODUCT MANUFACTURING ESTABLISHMENTS

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 mailing this form to FDA's Document Control Center (DCC) or electronically submitting via FDA's Tobacco Registration and Product Listing Module Next Generation (TRLM-NG) system **does not denote FDA authorization** for the marketing of tobacco products in the United States (U.S.). FDA does not consider listed products to be authorized for the legal sale and distribution in the U.S. unless they have an **FDA marketing authorization order in effect.***

Marketing a new tobacco product without an FDA marketing authorization order in effect is illegal and may be subject to enforcement.

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NOTICE

Please **type 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.

FDA strongly encourages you to submit your establishment registration and product list online using FDA's free TRLM-NG module. To create an Industry Account, please visit: https://trlm-ng-industry.fda.gov/login.

This system greatly streamlines the data entry process for 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 registrants to attach and track large numbers of material files for labeling, advertising, and consumer information submissions.

If you are unable to submit your establishment registration and product list online using TRLM-NG, Form FDA 3741 and FDA 3741b can be printed and mailed or saved to a USB flash drive or DVD, along with any material files, and mailed to FDA's Document Control Center, at the address below. Please note that should you require additional space for any section, 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 form 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 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 created 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 created 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)*

2. Provide the TRLM-NG Registration ID that FDA previously assigned*: RG_____
(Skip if this is an initial establishment registration and product list submission)

SECTION II – FORM FDA 3741 NAVIGATION GUIDE AND SUBMISSION CHECKLIST

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

The Form 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 and Acknowledgement.

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 registrant 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 Product List and Material File Submission	Update **Only** to Previously Submitted Establishment Registration Submission	Update **Only** to Previously Submitted Product List and/ or Material File Submission	Update to **Both** a Previously Submitted Establishment Registration **and** Previously Submitted Product List and/ or Material File Submission
I.	Submission Type	X	X	X	X
II.A.	Form FDA 3741 Navigation Guide	X	X	X	X
II.B.	Submission Checklist	X	X	X	X
II.C.	Acknowledgement	X	X	X	X
III.A.	Registrant Information for Initial Submission	X			
III.B.	TRLM-NG Secondary User Information for Initial Submission	X			
IV.A.	Establishment Information for Initial Submission	X			
IV.B.	Establishment Owner Information for Initial Submission	X			
IV.C.	Establishment Operator Information for Initial Submission	X			
V.	Product List Information for Initial Submission	X			
VI.	Material File Information for Initial Submission	X			
VII.A.	Updates to Registrant Information		X (if applicable)		X (if applicable)
VII.B.	Updates to TRLM-NG Secondary User Information		X (if applicable)		X (if applicable)
VIII.A.	Updates to Establishment Information		X (if applicable)		X (if applicable)
VIII.B.	Updates to Establishment Owner Information		X (if applicable)		X (if applicable)
VIII.C.	Updates to Establishment Operator Information		X (if applicable)		X (if applicable)
IX	Updates to Product List Information			X (if applicable)	X (if applicable)
X.	Updates to Material File Information			X (if applicable)	X (if applicable)
XI.	Certification Statement	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 Product List and Material File Submission	Update **Only** to Previously Submitted Establishment Registration Submission	Update **Only** to Previously Submitted Product List and/ or Material File Submission	Update to **Both** a Previously Submitted Establishment Registration **and** Previously Submitted Product List and/ or Material File Submission
I.	Submission Type				
II.A.	Form FDA 3741 Navigation Guide				
II.B.	Submission Checklist				
II.C.	Acknowledgement				
III.A.	Registrant Information for Initial Submission				
III.B.	TRLM-NG Secondary User Information for Initial Submission				
IV.A.	Establishment Information for Initial Submission				
IV.B.	Establishment Owner Information for Initial Submission				
IV.C.	Establishment Operator Information for Initial Submission				
V.	Product List Information for Initial Submission				
VI.	Material File Information for Initial Submission				
VII.A.	Updates to Registrant Information				
VII.B.	Updates to TRLM-NG Secondary User Information				
VIII.A.	Updates to Establishment Information				
VIII.B.	Updates to Establishment Owner Information				
VIII.C.	Updates to Establishment Operator Information				
IX	Updates to Product List Information				
X.	Updates to Material File Information				
XI.	Certification Statement				

Part C: Acknowledgement

1. ☐ **Acknowledgement*:** I acknowledge I have reviewed the FDA Form 3741 Navigation Guide, completed the Submission Checklist to reflect the type of information being provided or updated in this submission, and will submit the requested information in the sections relevant to my submission type.*

SECTION III – REGISTRATION INFORMATION FOR INITIAL SUBMISSION

Instructions for Section III – Registration Information for Initial Submission
Section III includes identifying the registrant (e.g., person registering a tobacco product manufacturing facility and submitting a product list for that establishment's commercially distributed tobacco products).

Part A: Registrant Information for Initial Submission

Instructions for Part A – Registrant Information for Initial Submission
The registrant is the entity seeking to register an establishment that it owns, operates, or is authorized to represent, which engages in the manufacture, preparation, compounding, or processing of tobacco products. 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.

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

Registrant's Point of Contact Information

1. First Name*		2. Middle Initial	3. Last Name*
4. Generational Suffix	5. Professional Suffix	6. Position Title*	
7. Business or Tribe Name*		8. Fax Number	
9. Phone Number (Work)*	10. Phone Number (Mobile)*	11. Email Address*	

Registrant's Association to Registered Establishment

12. What is the registrant's association to the establishment(s) being registered in this submission? *(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**
Responsible official authorized to represent a tobacco product manufacturing 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 designated by the registrant as additional individuals who will need access to review and/or update the registration and product list. In instances where the registrant is nonresponsive, FDA may contact the TRLM-NG secondary user for CTP registration and listing issues. Please provide all indicated information (is required) for each TRLM-NG secondary user being added to the registration. If more than one TRLM-NG secondary user needs to be added, submit additional sections for each additional user as needed.*

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

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

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

Designated TRLM-NG Secondary User's Point of Contact Information

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

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

8. Business or Tribe Name*	9. Fax Number

10. Phone Number (Work)*	11. Phone Number (Mobile)*	12. Email Address*

TRLM-NG Secondary User's Association to Registered Establishment

13. What is the TRLM-NG Secondary User's association to the establishment(s) being registered in this submission?* *(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**
Responsible official authorized to represent a tobacco product manufacturing establishment being registered.

14. Specify level of access the secondary user will need for the registration in TRLM-NG *(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
Section IV includes identifying the tobacco product establishment(s) and providing key information on their operations and a designated point of contact. Please complete this section for each establishment that engages in the manufacture, preparation, compounding, or processing of tobacco products.

Part A: Establishment Information for Initial Submission

Establishment Identification

1. Establishment Name (Legal Name)*	2. Does the establishment go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s): _____ ☐ No
3. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	4. Establishment D&B DUNS® Number *(if applicable)*

5. Establishment Business's Web Address or URL*

6. Date Establishment Began Manufacturing Tobacco Products for Commercial Distribution* *(mm/dd/yyyy)*

Establishment 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 mailing address and proceed to Establishment Point of Contact Information.

Establishment 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*

Designated Establishment Point of Contact

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

☐ Is the same as the registrant (*provide first and last name, then proceed to establishment details)*

☐ Is the same as the TRLM-NG Secondary User, (*provide first and last name, then proceed to establishment details)*

☐ Is not otherwise listed in previous sections *(provide information below)*

21. First Name*		22. Middle Initial	23. Last Name*
24. Generational Suffix	25. Professional Suffix	26. Position Title*	
27. Business or Tribe Name*		28. Fax Number	
29. Phone Number (Work)*	30. Phone Number (Mobile)*	31. Email Address*	

Establishment Details

32. Is the establishment an Electronic Nicotine Delivery System (ENDS) retailer which performs manufacturing activities (such as e-liquid mixing, bottling, packaging, labeling, and/or coil or device repairs) onsite? *(select one)**

☐ Yes ☐ No

33. Is the establishment located in a personal residence? *(select one)**

☐ Yes ☐ No

34. Is English the primary language spoken at the establishment? *(select one)**

☐ Yes ☐ No, primary language spoken: _____

35. Is the establishment located on Tribal lands or otherwise owned or operated by a Tribe?* *(select all that apply)*

☐ Located on Tribal lands *(proceed below)*

☐ Owned and/or operated by a Tribe or members of a Tribe *(proceed below)*

☐ Privately owned/operated *(skip Tribal Authority Point of Contact and proceed to Establishment Operations)*

☐ Not located on Tribal lands *(skip Tribal Authority Point of Contact and proceed to Establishment Operations)*

Designated Tribal Authority Point of Contact

36. Tribal Authority Point of Contact *(select all that apply)**

☐ Is the same as the registrant (*provide first and last name, then proceed to establishment operations)*

☐ Is the same as the TRLM-NG Secondary User
(*provide first and last name, then proceed to establishment operations)*

☐ Is the same as the establishment point of contact
(provide first and last name, then proceed to establishment operations)

☐ Is not otherwise listed in previous sections *(provide information below)*

37. First Name*	38. Middle Initial	39. Last Name*

40. Generational Suffix	41. Professional Suffix	42. Position Title*

43. Tribe Name*	44. Fax Number

45. Phone Number (Work)*	46. Phone Number (Mobile)*	47. Email Address*

Establishment Operations

48. Select whether the establishment manufacturers finished tobacco products or products for further manufacturing use *(select one)**

☐ Manufacturing of Finished Tobacco Products

☐ Manufacturing of Tobacco Products for Use in Further Manufacturing

☐ Manufacturing **Both** Finished Tobacco Products and Products for Use in Further Manufacturing

49. Select all operations in which the establishment engages*

General Operations

☐ Assembling, Modifying, or Repairing Tobacco Products

☐ Labeling/Re-Labeling Tobacco Products

☐ Packaging/Re-Packaging Tobacco Products

☐ Contract Manufacturing Tobacco Products

☐ Co-Packing (third party packaging/labeling) Tobacco Products

Product Specific Operations

☐ Blending, Casing, Processing, Mixing or Reconstituting Tobacco

☐ E-Liquid Production (mixing/blending nicotine, flavorings, PG/VG or other ingredients)

☐ E-Liquid Filling/Packaging (bottling or pod filling)

☐ Artisanal Pipe Making

☐ Slitting, Rolling, Printing, Perforating, Cutting (for RYO products)

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 (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 (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 (Specify) _____

☐ Storing Tobacco Products

☐ Testing Tobacco Products

☐ Advertising

☐ Other (specify) _____

Part B: Establishment Owner Information for Initial Submission

Instructions for Part B – Establishment Owner Information for Initial Submission
Provide details on who has an ownership interest in the establishment being registered.

Owner's Business Identification

1. Business Name (Legal Name)*	2. Does the business entity go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s): _____ ☐ No
3. Owner Business Headquarter's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	4. Owner's Business Headquarter's D&B DUNS® Number *(if applicable)*

Owner's Business Physical Address

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*

11. ☐ Select if mailing address is same as physical address. If the same, skip mailing address and proceed to Owner's Point of Contact Information.

Owner's Business Mailing Address

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

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

Owner's Designated Point of Contact Information

18. Owner's Designated Point of Contact *(select all that apply)**

☐ Is the same as the designated point of contact for the registrant.
(provide first and last name and then proceed to owner's business structure)

☐ Is the same as the designated point of contact for the TRLM-NG secondary user
(provide first and last name and then proceed to owner's business structure)

☐ Is the same as the designated point of contact for the establishment.
(provide first and last name and then proceed to owner's business structure)

☐ Is not otherwise listed in previous sections *(provide information below)*

19. First Name*	20. Middle Initial	21. Last Name*

22. Generational Suffix	23. Professional Suffix	24. Position Title*

25. Business or Tribe Name*	26. Fax Number

27. Phone Number (Work)*	28. Phone Number (Mobile)*	29. Email Address*

Owner's Business Structure

30. 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)*

☐ **Tribe** *(enter information on each Tribal Leader/Councilperson)*

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

Key Business Official #1

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #2

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #3

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #4

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #5

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Location of Formation of Legal Business Entity	
32. State of Formation (if in U.S.) *(optional)*	33. Territory and Country if outside U.S. *(optional)*

Part C: Establishment Operator Information for Initial Submission

Instructions for Part C – Establishment Operator Information for Initial Submission
Provide details on who has management authority of the establishment being registered.

Operator's Business Identification

1. Business Name (Legal Name)*	2. Does the business entity go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s): _____ ☐ No
3. Operator Business Headquarter's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	4. Operator Business Headquarter's D&B DUNS® Number *(if applicable)*

Operator's Business Physical Address

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*

11. ☐ Select if mailing address is same as physical address. If the same, skip mailing address and proceed to Operator Point of Contact Information.

Operator's Business Mailing Address

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

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

Operator's Designated Point of Contact Information

18. Operator's Designated Point of Contact *(select all that apply)**

- ☐ Is the same as the designated point of contact for the registrant. *(provide first and last name and then proceed to operator's business structure)*
- ☐ Is the same as the designated point of contact for the TRLM-NG secondary user *(provide first and last name and then proceed to operator's business structure)*
- ☐ Is the same as the designated point of contact for the establishment *(provide first and last name and then proceed to operator's business structure)*
- ☐ Is the same as the owner's designated point of contact *(provide first and last name and then proceed to operator's business structure)*
- ☐ Is not otherwise listed in previous sections *(provide information below)*

19. First Name*		20. Middle Initial	21. Last Name*
22. Generational Suffix	23. Professional Suffix	24. Position Title*	
25. Business or Tribe Name*		26. Phone Number (Work)*	
27. Phone Number (Mobile)*	28. Fax Number	29. Email Address*	

Operator's Business Structure

30. 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)*
- ☐ **Tribe** *(enter information on each Tribal Leader/Councilperson)*

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

Key Business Official #1

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

Key Business Official #2

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

Key Business Official #3

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

Key Business Official #4

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

Key Business Official #5

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Location of Formation of Legal Business Entity

32. State of Formation (if in U.S.) *(optional)*	33. Territory and Country (if outside U.S) *(optional)*

SECTION V – PRODUCT LIST INFORMATION FOR INITIAL SUBMISSION

Instructions for Section V – Product List Information for Initial Submission

Provide the requested product list information for every product manufactured at each establishment being registered with FDA. Please clearly indicate which tobacco product(s) are associated with each establishment information was provided for in Section IV. Every product listed must have a universal product code (UPC), product category and subcategory, package type, characterizing flavor (tobacco, menthol, flavored [i.e., other than just tobacco or menthol alone] or unflavored), a way to quantify the product amount (i.e., by providing the numeric value and units for either product quantity, product quantity mass, portion count, or portion mass as applicable for the product subcategory), and an indication of the nicotine source (i.e., tobacco derived nicotine, non-tobacco derived nicotine, both, or 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 3741b product list spreadsheet for the selectable options per field for each product subcategory.

Note: You can use 3741b to organize and upload your product information and properties directly into TRLM-NG or save to USB/DVD to mail to DCC. If you are submitting this form by mail, for each product you must also provide the Associated Establishment Information, Manufacturing and Commercial Distribution Status, and Product Marketing Authorization information as indicated below. If using TRLM-NG to submit, these data elements will be collected after you upload your 3741b product list spreadsheet.

Product Identifiers

1. Product Name*	2. Brand Name*	3. Sub-brand Name*

4. Universal Product Code (UPC)*	5. Alternative Industry Product Identification Number

6. Alternative Industry Product Identification Number Type *(select one)*

- ☐ SKU
- ☐ Catalog or Item #
- ☐ Other (Specify) _____

7. Product Category and Subcategory*

☐ **Cigarettes**
- ☐ Filtered Cigarettes
- ☐ Non-Filtered Cigarettes
- ☐ Other (Specify) _____

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

☐ **Electronic Nicotine Delivery Systems (ENDS)/Vapes**
- ☐ Closed E-Cigarette
- ☐ Closed E-Liquid
- ☐ ENDS Component
- ☐ Open E-Cigarette
- ☐ Open E-Liquid
- ☐ Other (Specify) _____

☐ **Heated Tobacco Products (HTP)**
- ☐ Closed HTP
- ☐ Open HTP
- ☐ HTP Consumable
- ☐ HTP Component
- ☐ Other (Specify) _____

☐ **Pipe Tobacco Products**
- ☐ Pipe
- ☐ Pipe Component
- ☐ Pipe Tobacco Filler
- ☐ 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
- ☐ 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
- ☐ Other (Specify) _____

☐ **Waterpipe Tobacco Products**
- ☐ Waterpipe
- ☐ Waterpipe Component
- ☐ Waterpipe Heat Source
- ☐ Waterpipe Tobacco Filler
- ☐ Other (Specify) _____

☐ **Oral Nicotine Products**
- ☐ Nicotine Pouch
- ☐ Other (Specify) _____

☐ **Other Products**

(Specify) _____

8. Intent of Use* *(e.g., consumer use or for further manufacturing)*

Product Attributes/Properties

9. Package Type*

Product Quantity*

10. Product Quantity *(Numeric value and units*)

11. Product Quantity Mass *(Numeric value and units*)

12. Portion Count *(Numeric value and units*)

13. Portion Mass *(Numeric value and units*)

Product Flavor

14. Characterizing Flavor* ***(select one)***

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

15. Flavor Name *(if flavored*)	16. Flavor Description *(if flavored*)

Product Nicotine Attributes

17. Nicotine Concentration *(Numeric value and units*)	18. Nicotine Source*

E-Liquid Concentration (if applicable)

19. PG *(Numeric value)*	20. VG *(Numeric value)*	21. E-Liquid Volume *(Numeric value and units)*

Device/Battery Information (if applicable)

22. Wattage *(Numeric value and units)*	23. Battery Capacity *(Numeric value and units)*

Length (if applicable)

24. Length Description	25. Length *(Numeric value and units)*

Width (as applicable)

26. Width *(Numeric value and units)*

Diameter (as applicable)

27. Diameter Description	28. Diameter Format	29. Diameter *(Numeric value and units)*

Height (as applicable)

30. Height *(Numeric value and units)*

Portion Thickness (as applicable)

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

Other (as applicable)

32. Tobacco Cut Style	33. Filter Ventilation *(Percentage)*	34. Number of Hoses
35. Source of Energy	36. Wrapper Material	
37. Tip Type	38. Additional Properties	

Associated Establishment Information

39. Manufacturing Establishment Name*	40. Manufacturing Establishment Facility Establishment Identifier (FEI) Number
41. Street Address Line 1*	42. Street Address Line 2 *(Apartment, Suite, Building Number)*

43. City*	44. State, Province, or Territory*	45. Country*	46. ZIP or Postal Code*

Manufacturing and Commercial Distribution Status

47. Date Introduced for Commercial Distribution* *(mm/dd/yyyy)*

Product Marketing Authorization

48. FDA Submission Tracking Number (STN) and Product Identifier (PD) Number*	49. If No STN-PD#, Provide Reason
50. Submitter Name	51. Applicant Name

52. Product Name as Appeared on Marketing Authorization or Exemption

SECTION VI – MATERIAL FILE INFORMATION FOR INITIAL SUBMISSION

Instructions for Section VI – Material File Information for Initial Submission
Use the fields below to provide the requested information on your labeling, consumer information, and advertising material files associated with your listed products. Files themselves will need to be uploaded electronically via TRLM-NG or mailed as a hard copy or USB/DVD to DCC.

Material File Identifiers

1. Material File Name*	2. Unique ID or Internal ID*	3. Date First Disseminated* *(mm/dd/yyy)*

Material File Information

4. Material File Title*	5. Material File Description*

6. Material File Category and Type*

☐ **Labeling**
- ☐ Product Labeling
- ☐ Carton
- ☐ Outer Container
- ☐ Wrapper
- ☐ Affixed Tag
- ☐ Shipping and Packaging
- ☐ Cigar Point of Sale Sign
- ☐ Cigar Box
- ☐ Other (Specify) _____

☐ **Advertising**
- ☐ Website or Banner
- ☐ Digital
- ☐ Social Media
- ☐ Point of Sale
- ☐ Magazine, Periodical, or Print
- ☐ Coupons
- ☐ Email
- ☐ Brochure
- ☐ Mobile App
- ☐ Flyer or Handout
- ☐ Large Sign
- ☐ Small Sign
- ☐ Other (Specify) _____

☐ **Consumer Information**
- ☐ Brochure or Pamphlet
- ☐ Instructions
- ☐ Catalog
- ☐ Cautions or Warnings
- ☐ Reviews or Feedback
- ☐ Press Release
- ☐ Business Card
- ☐ Coupons, Rewards, or Loyalty Cards
- ☐ Digital Information
- ☐ Point of Sale Customer Information
- ☐ Trade Show Material
- ☐ Other (Specify)_____

7. URL *(if digital, social media, or website)*

8. Location of Labeling* *(select one)*

☐ Top ☐ Front ☐ Side ☐ Back ☐ Bottom ☐ Other_____

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)*

Associated Product Identifiers	
12. Product Name*	13. Universal Product Code (UPC)*
14. Alternative Industry Product Identification Number	15. Alternative Industry Product Identification Number Type *(select one)* ☐ SKU ☐ Catalog or Item # ☐ Other (Specify) _____

SECTION VII – UPDATES TO REGISTRATION INFORMATION

Part A: Updates to Registrant Information

Instructions for Part A – Updates to Registrant Information
Please note, all references to the "registrant" in this part are specifically referring to their role as the TRLM-NG account manager. Use this section if the original registrant is no longer affiliated with the registered establishment and the previous TRLM-NG account manager role in the system needs to be transferred to a new registrant to resume updating the registration.

1. Have there been any changes to who is serving as the registrant/TRLM-NG account manager or their information (see Section III.A) since the last submission? *(select one)**

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

☐ No *(skip to Section VII, Part B: Updates to TRLM-NG Secondary User Information)*

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

2. Select reason for registrant update *(select one)**

☐ Updating information for existing registrant
(complete fields 3-14, then proceed to VII.B – Updates to TRLM-NG Secondary User Information)

☐ Transferring registrant role to another individual
(complete fields 15-26, then proceed to VII.B – Updates to TRLM-NG Secondary User Information)

Updated Registrant's Point of Contact Information		
3. First Name* ☐ No Update	4. Middle Initial ☐ No Update	5. Last Name* ☐ No Update
6. Generational Suffix ☐ No Update	7. Professional Suffix ☐ No Update	8. Position Title* ☐ No Update
9. Business or Tribe Name* ☐ No Update		10. Fax Number ☐ No Update
11. Phone Number (Work)* ☐ No Update	12. Phone Number (Mobile)* ☐ No Update	13. Email Address* ☐ No Update

Updated Registrant's Association to Registered Establishment

14. What is the registrant's association to the establishment(s) being registered in this submission? *(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**
Responsible official authorized to represent a tobacco product manufacturing establishment being registered.

New Registrant's Designated Point of Contact for the Registration

15. First Name*	16. Middle Initial	17. Last Name*

18. Generational Suffix	19. Professional Suffix	20. Position Title*

21. Business or Tribe Name*	22. Fax Number

23. Phone Number (Work)*	24. Phone Number (Mobile)*	25. Email Address*

26. What is the registrant's association to the establishment(s) being registered in this submission? *(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**
Responsible official authorized to represent a tobacco product manufacturing establishment being registered.

Part B: Updates to TRLM-NG Secondary User(s) Information

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

The TRLM-NG secondary user(s) is/are designated by the registrant as additional individuals who will need access to review and/or update the establishment registration and product list information. In instances where the registrant is non-responsive, FDA may contact the TRLM-NG secondary user for CTP registration and product listing issues.

Provide all indicated information (is required) for each TRLM-NG secondary user being 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 information (see Section III.B) since the last submission *(select one)* *

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

☐ No *(skip to Section VIII.A – Updates to Establishment Information)*

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

2. Select reason for TRLM-NG secondary user update *(select one)**

☐ Updating information for existing TRLM-NG secondary user
(complete fields 3-5 to identify the TRLM-NG secondary user whose information needs to be updated and provide the applicable updates in fields 6-18. Then proceed to VIII.A – Updates to Establishment Information)

☐ Adding new TRLM-NG secondary user
(complete fields 19-30, then proceed to VIII.A – Updates to Establishment Information)

☐ Replacing or removing TRLM-NG secondary user
(complete fields 3-5 to identify the TRLM-NG secondary user who needs to be removed and skip to field 18 to select "revoke access and remove user". If applicable, provide new TRLM-NG secondary information in fields 19-30)

☐ Changing TRLM-NG secondary user access
(complete fields 3-5 to identify the TRLM-NG secondary user whose access level needs to be updated and select the appropriate access level in fields 18. Then proceed to VIII.A – Updates to Establishment Information.)

Identification of TRLM-NG Secondary User to Update

3. First Name*	4. Last Name*	5. Email address*

Updated TRLM-NG Secondary User 's Point of Contact Information

6. First Name* ☐ No Update	7. Middle Initial ☐ No Update	8. Last Name* ☐ No Update

9. Generational Suffix ☐ No Update	10. Professional Suffix ☐ No Update	11. Position Title* ☐ No Update

12. Business or Tribe Name* ☐ No Update	13. Fax Number ☐ No Update

14. Phone Number (Work)* ☐ No Update	15. Phone Number (Mobile)* ☐ No Update	16. Email Address* ☐ No Update

Updated TRLM-NG Secondary User's Association to Registered Establishment

17. What is the updated TRLM-NG Secondary User's association to the establishment(s) being registered in this submission? *(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**
Responsible official authorized to represent a tobacco product manufacturing establishment being registered.

Updates to TRLM-NG Secondary User's Access

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

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

☐ **Review and edit:** Has full access, can fill in for primary account manager and edit, certify, and submit registration and product listing information.

☐ **Revoke access and remove TRLM-NG secondary user:** Removes the previously designated secondary user from the registration so they can no longer view or edit the registration and product listing information.

New TRLM-NG Secondary User 's Point of Contact Information		
19. First Name*	20. Middle Initial	21. Last Name*

22. Generational Suffix	23. Professional Suffix	24. Position Title*

25. Business or Tribe Name*	26. Fax Number

27. Phone Number (Work)*	28. Phone Number (Mobile)*	29. Email Address*

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

30. What is the updated TRLM-NG Secondary User's association to the establishment(s) being registered in this submission? *(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**
Responsible official authorized to represent a tobacco product manufacturing establishment being registered.

SECTION VIII – UPDATES TO ESTABLISHMENT INFORMATION

Part A: Updates to Establishment Information

Instructions for Part A – Updates to Establishment Information
Provide all indicated information (is required) for each establishment being updated or added to the registration. Submit additional copies of this section as needed for each additional establishment added or for each additional establishment whose information needs to be updated.*

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

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

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

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

2. Select the applicable statement for this submission*

☐ Change in establishment information

☐ Updated to establishment manufacturing status

☐ An additional establishment needs to be added to the registration

New Establishment to Add to Registration

New Establishment's Identification

3. Establishment Name (Legal Name)*	4. Does the establishment go by any other name?*
	☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s): _____ ☐ No

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

7. Establishment Business's Web Address or URL*

8. Date Establishment Began Manufacturing Tobacco Products for Commercial Distribution* *(mm/dd/yyyy)*

New Establishment Physical Address

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*

15. ☐ Select if mailing address is same as physical address. If the same, skip mailing address and proceed to Establishment Point of Contact Information.

New Establishment Business Mailing 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*

Designated New Establishment Point of Contact

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

☐ Is the same as the registrant (*provide first and last name, then proceed to establishment details)*

☐ Is the same as the TRLM-NG Secondary User (*provide first and last name, then proceed to establishment details)*

☐ Is not otherwise listed in previous sections *(provide information below)*

23. First Name*		24. Middle Initial	25. Last Name*
26. Generational Suffix	27. Professional Suffix	28. Position Title*	
29. Business or Tribe Name*		30. Fax Number	
31. Phone Number (Work)*	32. Phone Number (Mobile)*	33. Email Address*	

New Establishment Details Questions

34. Is the establishment an Electronic Nicotine Delivery System (ENDS) retailer which performs manufacturing activities (such as e-liquid mixing, bottling, packaging, labeling, and/or coil or device repairs) onsite? *(select one)**

☐ Yes ☐ No

35. Is the establishment located in a personal residence? *(select one)**

☐ Yes ☐ No

36. Is English the primary language spoken at the establishment? *(select one)**

☐ Yes ☐ No, primary language spoken: _____

37. Is the establishment located on Tribal lands or otherwise owned or operated by a Tribe?* *(select all that apply)*

☐ Located on Tribal lands *(proceed below)*

☐ Owned and/or operated by a Tribe or members of a Tribe *(proceed below)*

☐ Privately owned/operated *(skip Tribal Authority Point of Contact, and proceed to Establishment Operations)*

☐ Not located on Tribal lands *(skip Tribal Authority Point of Contact, and proceed to Establishment Operations)*

Designated Tribal Authority Point of Contact

38. Tribal Authority Point of Contact *(select all that apply)**

☐ Is the same as the registrant *(provide first and last name, then proceed to establishment operations)*

☐ Is the same as the TRLM-NG Secondary User
(provide first and last name, then proceed to establishment operations)

☐ Is the same as the establishment point of contact
(provide first and last name, then proceed to establishment operations)

☐ Is not otherwise listed in previous sections *(provide information below)*

39. First Name*	40. Middle Initial	41. Last Name*

42. Generational Suffix	43. Professional Suffix	44. Position Title*

45. Tribe Name*	46. Fax Number

47. Phone Number (Work)*	48. Phone Number (Mobile)*	49. Email Address*

New Establishment Operations

50. Select whether the establishment manufacturers finished tobacco products or products for further manufacturing use *(select one)**

☐ Manufacturing of Finished Tobacco Products

☐ Manufacturing of Tobacco Products for Use in Further Manufacturing

☐ Manufacturing **Both** Finished Tobacco Products and Products for Use in Further Manufacturing

51. Select all operations in which the establishment engages*

General Operations

- ☐ Assembling, Modifying, or Repairing Tobacco Products
- ☐ Labeling/Re-Labeling Tobacco Products
- ☐ Packaging/Re-Packaging Tobacco Products
- ☐ Contract Manufacturing Tobacco Products
- ☐ Co-Packing (third party packaging/labeling) Tobacco Products

Product Specific Operations

- ☐ Blending, Casing, Processing, Mixing, or Reconstituting Tobacco
- ☐ E-Liquid Production (mixing/blending nicotine, flavorings, PG/VG or other ingredients)
- ☐ E-Liquid Filling/Packaging (bottling or pod filling)
- ☐ Artisanal Pipe Making
- ☐ Slitting, Rolling, Printing, Perforating, Cutting (for RYO products)

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 (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 (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 (specify) _____

☐ Storing Tobacco Products

☐ Testing Tobacco Products

☐ Advertising

☐ Other (specify) _____

52. Effective Date of Change for when added Establishment began manufacturing tobacco products *(mm/dd/yyyy)**

Updates to Establishment Information

Identification of Establishment to Update

53. Establishment Name (Legal Name)* ☐ No Update	54. Establishment Name (DBA Name)* ☐ No Update
55. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number* ☐ No Update	56. Establishment D&B DUNS® Number *(if applicable)* ☐ No Update

57. Establishment Business's Web Address or URL *(optional)* ☐ No Update

58. Date Establishment Began Manufacturing Tobacco Products for Commercial Distribution* *(mm/dd/yyyy)* ☐ No Update

Updates to Establishment Physical Address

59. Street Address Line 1* ☐ No Update	60. Street Address Line 2 *(Apartment, Suite, Building Number)* ☐ No Update		
61. City* ☐ No Update	62. State, Province, or Territory* ☐ No Update	63. Country* ☐ No Update	64. ZIP or Postal Code* ☐ No Update

65. ☐ Select if mailing address is same as physical address. If the same, skip mailing address and proceed to Establishment Point of Contact Information. ☐ No Update

Updates to Establishment Business Mailing Address

66. Street Address Line 1* ☐ No Update	67. Street Address Line 2 *(Apartment, Suite, Building Number)* ☐ No Update

68. City* ☐ No Update	69. State, Province, or Territory* ☐ No Update	70. Country* ☐ No Update	71. ZIP or Postal Code* ☐ No Update

Designated Establishment Point of Contact

72. Establishment Point of Contact *(select all that apply)** ☐ No Update

- ☐ Is the same as the registrant (*provide first and last name, then proceed to establishment details)*
- ☐ Is the same as the TRLM-NG Secondary User (*provide first and last name, then proceed to establishment details)*
- ☐ Is not otherwise listed in previous sections *(provide information below)*

73. First Name ☐ No Update	74. Middle Initial ☐ No Update	75. Last Name ☐ No Update

76. Generational Suffix ☐ No Update	77. Professional Suffix ☐ No Update	78. Position Title* ☐ No Update

79. Business or Tribe Name* ☐ No Update	80. Fax Number ☐ No Update

81. Phone Number (Work)* ☐ No Update	82. Phone Number (Mobile)* ☐ No Update	83. Email Address* ☐ No Update

Updates to Establishment Details Questions

84. Is the establishment an Electronic Nicotine Delivery System (ENDS) retailer which performs manufacturing activities (such as e-liquid mixing, bottling, packaging, labeling, and/or coil or device repairs) onsite? *(select one)** ☐ No Update

☐ Yes ☐ No

85. Is the establishment located in a personal residence? *(select one)** ☐ No Update

☐ Yes ☐ No

86. Is English the primary language spoken at the establishment? *(select one)** ☐ No Update

☐ Yes ☐ No, primary language spoken: _____

87. Is the establishment located on Tribal lands or otherwise owned or operated by a Tribe?* ☐ No Update

- ☐ Located on Tribal lands *(proceed below)*
- ☐ Owned and/or operated by a Tribe or members of a Tribe *(proceed below)*
- ☐ Privately owned/operated *(skip Tribal Authority Point of Contact, and proceed to Establishment Operations)*
- ☐ Not located on Tribal lands *(skip Tribal Authority Point of Contact, and proceed to Establishment Operations)*

Designated Tribal Authority Point of Contact

88. Tribal Authority Point of Contact *(select all that apply)** ☐ No Update

- ☐ Is the same as the registrant *(provide first and last name, then proceed to establishment operations)*
- ☐ Is the same as the TRLM-NG Secondary User *(provide first and last name, then proceed to establishment operations)*
- ☐ Is the same as the establishment point of contact *(provide first and last name, then proceed to establishment operations)*
- ☐ Is not otherwise listed in previous sections *(provide information below)*

89. First Name* ☐ No Update	90. Middle Initial ☐ No Update	91. Last Name* ☐ No Update

92. Generational Suffix ☐ No Update	93. Professional Suffix ☐ No Update	94. Position Title* ☐ No Update

95. Tribe Name* ☐ No Update	96. Fax Number ☐ No Update

97. Phone Number (Work)* ☐ No Update	98. Phone Number (Mobile)* ☐ No Update	99. Email Address* ☐ No Update

Updated Establishment Operations

100. Select whether the establishment manufacturers finished tobacco products or products for further manufacturing use *(select one)**

- ☐ Manufacturing of Finished Tobacco Products
- ☐ Manufacturing of Tobacco Products for Use in Further Manufacturing
- ☐ Manufacturing **Both** Finished Tobacco Products and Products for Use in Further Manufacturing ☐ No Update

101. Select all operations in which the establishment engages* ☐ No Update

General Operations

- ☐ Assembling, Modifying, or Repairing Tobacco Products
- ☐ Labeling/Re-Labeling Tobacco Products
- ☐ Packaging/Re-Packaging Tobacco Products
- ☐ Contract Manufacturing Tobacco Products
- ☐ Co-Packing (third party packaging/labeling) Tobacco Products

Product Specific Operations

- ☐ Blending, Casing, Processing, Mixing, or Reconstituting Tobacco
- ☐ E-Liquid Production (mixing/blending nicotine, flavorings, PG/VG or other ingredients)
- ☐ E-Liquid Filling/Packaging (bottling or pod filling)
- ☐ Artisanal Pipe Making
- ☐ Slitting, Rolling, Printing, Perforating, Cutting (for RYO products)

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 (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 (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 (specify) _____

☐ Storing Tobacco Products

☐ Testing Tobacco Products

☐ Advertising

☐ Other (specify) _____

102. Effective Date of Change for when new Establishment began manufacturing tobacco products *(mm/dd/yyyy)**

Updates to Existing Establishment's Manufacturing Status

Manufacturing Status

Please indicate your establishment's current manufacturing status

☐ **Reactivate – Establishment has resumed manufacturing**

Establishment Name to be reactivated

Establishment FDA-Assigned Facility Establishment (FEI) Number to be reactivated	Establishment D&B DUNS® Number to be reactivated

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

City	State, Province, or Territory	Country	ZIP or Postal Code

Date Resumed Manufacturing *(mm/dd/yyyy)*

☐ **Active – Establishment relocated (same establishment, new address)**

Date Manufacturing Ceased at Previous Site *(mm/dd/yyyy)*	Date Manufacturing Activites Began at New Site *(mm/dd/yyyy)*

☐ **Inactive – Establishment has ceased manufacturing** (provide inactivation reason below)

Date Manufacturing Ceased *(mm/dd/yyyy)*

☐ **Inactive – Establishment has transferred operations to a different establishment (new establishment, new address, different owner and/or operator)** (provide inactivation reason below)

Date Manufacturing Ceased at Previous Site *(mm/dd/yyyy)*	Date Manufacturing Activites Began at New Site *(mm/dd/yyyy)*

Provide the RG ID for the new establishment
(if manufacturing transferred to another establishment on a different registration) (if applicable)

Establishment Inactivation Reason:

☐ Data Clean-up

Establishment was included on more than one registration (associated with more than one registration 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 registration ID # where the establishment information will be kept up to date.

- Surviving Registration ID #: _____
- Surviving Establishment Name:_____
- Surviving Establishment FEI #: _____
- Registration ID #'s where duplicate establishment(s) are being inactivated: _____

☐ 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 packing, re-packaging, labeling, or re-labeling, and/or switching to only manufacturing products that are neither tobacco products, nor component or parts of tobacco products.

☐ Manufacturing only tobacco products that are not finished tobacco products

If all products manufactured at the Establishment are sold or distributed solely for further manufacturing of tobacco products.

☐ Out of business

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 Reason: *(if inactivating last active establishment on registration, inactivate the registration)*

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.)

☐ 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 registration ID # of the duplicates and which is the surviving registration that will be kept up to date and confirm the establishments (name, address, FEI #) that should be on the surviving registration.

- TRLM-NG Registration ID #(s) of duplicates that will be inactivated: _____
- Surviving Registration ID # that will be kept up to date: _____
- Surviving Establishment Name(s): _____
- Surviving Establishment address(es): _____
- Surviving Establishment FEI #(s): _____

☐ 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.

☐ Manufacturing only tobacco products that are not finished tobacco products

If all products manufactured at the Establishment are sold or distributed solely for further manufacturing of tobacco products.

☐ 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 a registration for a reason not indicated above, specify.

Date of registration inactivation: *(mm/dd/yyyy)*

Part B: Updates to Establishment Owner Information

Instructions for Part B – Updates to Establishment Owner Information

Provide updated information if there have been changes to who has an ownership interest in the registered establishment(s). Owner information, which includes the owner's name, owner's designated point of contact information, and owner's business structure, will be needed for each updated establishment on the registration. Submit additional sheets for each establishment owner that needs to be updated.

1. Have there been any changes to the Establishment(s) Owner Information (see Section IV, Part B) since the last submission? *(select one)**

☐ Yes – *(provide the effective date of change and proceed below to identify which establishment's owner information has changed and provide updated information)*

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

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

Identify the currently registered establishment whose owner information needs to be updated.*

2. Establishment Name (Legal Name)*	3. Does the establishment go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s): _____ ☐ No

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

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*

Update Establishment Owner Information

12. Owner's Business Identification*

☐ Update needed *(proceed below)* ☐ No Update *(skip to Owner's Business Physical Address)*

Business Name (Legal Name)*	Does the business entity go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s: _____ ☐ No

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

13. Owner's Business Physical Address*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Owner's Business Mailing Address)*

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

City*	State, Province, or Territory*	Country*	ZIP or Postal Code*

☐ Select if mailing address is same as physical address. If the same, skip mailing address and proceed to Owner's Point of Contact Information.

14. Owner's Business Mailing Address*

☐ Update needed *(proceed below)* ☐ No Update *(skip to Owner's Designated Point of Contact Information)*

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

City*	State, Province, or Territory*	Country*	ZIP or Postal Code*

15. Owner's Designated Point of Contact Information*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Owner's Business Structure)*

Owner's Designated Point of Contact *(select all that apply)**

☐ Is the same as the designated point of contact for the registrant
(provide first and last name and then proceed to owner's business structure)

☐ Is the same as the designated point of contact for the TRLM-NG secondary user
(provide first and last name and then proceed to owner's business structure)

☐ Is the same as the designated point of contact for the establishment
(provide first and last name and then proceed to owner's business structure)

☐ Is not otherwise listed in previous sections *(provide information below)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*

Business or Tribe Name*	Fax Number

Phone Number (Work)*	Phone Number (Mobile)*	Email Address*

16. Owner's Business Structure*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Officials)*

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)*

☐ **Tribe** *(enter information on each Tribal Leader/Councilperson)*

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

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Location of Formation of Owner's Business)*

Key Business Official #1

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Official #2)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #2

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Official #3)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #3

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Official #4)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #4

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Official #5)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #5

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Location of Formation of Owner's Business)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

18. Location of Formation of Legal Business Entity

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Part C – Updates to Establishment Operator Information)*

State of Formation (if in U.S.) *(Optional)*	Territory and Country (if outside U.S.) *(Optional)*

Part C: Updates to Establishment Operator Information

Instructions for Part C – Updates to Establishment Operator Information

Provide updated information if there have been changes to who has management authority in the registered establishment(s). Operator information, which includes the operator's name, operator's designated point of contact information, and operator's business structure, will be needed for each updated establishment on the registration. Submit additional sheets for each establishment operator that needs to be updated.

1. Have there been any changes to the Establishment(s) Operator Information (see Section IV, Part C) since the last submission? *(select one)**

☐ Yes – (*proceed below to identify which establishment's operator information has changed and provide the updated information)*

☐ No – *(skip to Section IX – Updates to Product List Information)*

Identify the currently registered establishment whose operator information needs to be updated.*

2. Establishment Name (Legal Name)*	3. Does the establishment go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s): _____ ☐ No
4. Establishment FDA-Assigned Facility Establishment Identifier (FEI) Number*	5. Establishment D&B DUNS® Number *(if applicable)*
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*

Update Establishment Operator Information

12. Operator's Business Identification*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Operator's Business Physical Address)*

Business Name (Legal Name)*	Does the business entity go by any other name?* ☐ Yes, provide alternate business name(s), tradename(s), doing business as (dba) name(s: _____ ☐ No
Operator's Business Headquarter's FDA-Assigned Facility Establishment Identifier (FEI) Number *(if applicable)*	Operator's Business Headquarter's D&B DUNS® Number *(if applicable)*

13. Operator's Business Physical Address*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Operator's Business Mailing Address)*

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

City*	State, Province, or Territory*	Country*	ZIP or Postal Code*

☐ Select if mailing address is same as physical address. If the same, skip Mailing Address and proceed to Operator's Point of Contact Information.

14. Operator's Business Mailing Address*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Operator's Designated Point of Contact Information)*

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

City*	State, Province, or Territory*	Country*	ZIP or Postal Code*

15. Operator's Designated Point of Contact Information*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Operator's Business Structure)*

Operator's Designated Point of Contact *(select all that apply)**

☐ Is the same as the designated point of contact for the registrant
(provide first and last name and then proceed to operator's business structure)

☐ Is the same as the designated point of contact for the TRLM-NG secondary user
(provide first and last name and then proceed to operator's business structure)

☐ Is the same as the designated point of contact for the establishment
(provide first and last name and then proceed to operator's business structure)

☐ Is not otherwise listed in previous sections *(provide information below)*

First Name*		Middle Initial	Last Name*
Generational Suffix	Professional Suffix	Position Title*	
Business or Tribe Name*		Fax Number	
Phone Number (Work)*	Phone Number (Mobile)*	Email Address*	

16. Operator's Business Structure*

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Officials)*

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)*

☐ **Tribe** *(enter information on each Tribal Leader/Councilperson)*

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

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Location of Formation of Operator's Business)*

Key Business Official #1

☐ Update Needed *(proceed below)* ☐ No Update *(skip to Key Business Official #2)*

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

Key Business Official #2

☐ Update needed *(proceed below)* ☐ No Update *(skip to Key Business Official #3)*

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

Key Business Official #3

☐ Update needed *(proceed below)* ☐ No Update *(skip to Key Business Official #4)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #4

☐ Update needed *(proceed below)* ☐ No Update *(skip to Key Business Official #5)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

Key Business Official #5

☐ Update needed *(proceed below)* ☐ No Update *(skip to Location of Formation of Owner's Business)*

First Name*	Middle Initial	Last Name*

Generational Suffix	Professional Suffix	Position Title*	Business or Tribe Name*

18. Location of Formation of Legal Business Entity

☐ Update needed *(proceed below)* ☐ No Update *(skip to Section IX – Updates to Product List)*

State of Formation (if in U.S.) *(Optional)*	Territory and Country (if outside U.S.) *(Optional)*

SECTION IX – UPDATES TO PRODUCT LIST INFORMATION

Instructions for Section IX

Provide information below on the type of change (i.e., adding new product, updating existing product details, updating product marketing status, etc.).

1. Have there been any changes to the Product List since the last submission?*

☐ Yes – *(proceed below to identify changes and provide updated information)*

☐ No – *(skip to Section X – Updates to Material File Information)*

2. Since your last submission, are any of the following true *(select all that apply)*?*

☐ Product name, identifiers, or attributes have changed

☐ A new product was introduced into commercial distribution

☐ A product was removed from commercial distribution *(inactivating product)*

☐ A product was reintroduced into commercial distribution or manufacturing resumed of previously discontinued product *(reactivating product)*

☐ Product is now associated with another establishment on this same registration

☐ Product is now associated with another establishment on a different registration

☐ Product manufacturing has transferred to a new manufacturing site

☐ Manufacturing of product has ceased, but remaining product is still being distributed by a third party

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

Fields Impacted*

Value on Last Submission	Updated Value for Current Submission	
Product Identification	**Product Identification**	
Product Name	☐ No Update	Product Name
Brand Name/Sub-brand	☐ No Update	Brand Name/Sub-brand
Universal Product Code (UPC)	☐ No Update	Universal Product Code (UPC)
Alternative Industry Product Identification #	☐ No Update	Alternative Industry Product Identification #
Product Category	☐ No Update	Product Category
Product Subcategory	☐ No Update	Product Subcategory
Intent of Use	☐ No Update	Intent of Use
Product Attributes	**Product Attributes**	
Package Type	☐ No Update	Package Type
Product Quantity	☐ No Update	Product Quantity
Product Quantity Mass	☐ No Update	Product Quantity Mass
Portion Count	☐ No Update	Portion Count
Portion Mass	☐ No Update	Portion Mass
Characterizing Flavor	☐ No Update	Characterizing Flavor
Flavor Name (if flavored)	☐ No Update	Flavor Name (if flavored)
Flavor Description (if flavored)	☐ No Update	Flavor Description (if flavored)

Value on Last Submission	Updated Value for Current Submission	
Nicotine Concentration	☐ No Update	Nicotine Concentration
Nicotine Source	☐ No Update	Nicotine Source
%PG	☐ No Update	%PG
%VG	☐ No Update	%VG
E-Liquid Volume	☐ No Update	E-Liquid Volume
Wattage	☐ No Update	Wattage
Battery Capacity	☐ No Update	Battery Capacity
Length Description	☐ No Update	Length Description
Length (numeric value and units)	☐ No Update	Length (numeric value and units)
Width (numeric value and units)	☐ No Update	Width (numeric value and units)
Diameter Description	☐ No Update	Diameter Description
Diameter Format	☐ No Update	Diameter Format
Diameter (numeric value and units)	☐ No Update	Diameter (numeric value and units)
Height	☐ No Update	Height
Portion Thickness	☐ No Update	Portion Thickness
Tobacco Cut Style	☐ No Update	Tobacco Cut Style
Filter Ventilation	☐ No Update	Filter Ventilation
# of Hoses	☐ No Update	# of Hoses

Value on Last Submission	Updated Value for Current Submission	
Source of Energy	☐ No Update	Source of Energy
Wrapper Material	☐ No Update	Wrapper Material
Tip Type	☐ No Update	Tip Type
Additional Properties	☐ No Update	Additional Properties
Associated Establishments	**Associated Establishments**	
Associated Establishment Name	☐ No Update	Associated Establishment Name
Associated Establishment FEI#	☐ No Update	Associated Establishment FEI#
Associated Establishment Address	☐ No Update	Associated Establishment Address
Manufacturing and Commercial Distribution Status	**Manufacturing and Commercial Distribution Status**	
Date Introduced for Commercial Distribution *(mm/dd/yyyy)*	☐ No Update	Date Introduced for Commercial Distribution *(mm/dd/yyyy)*
Product Marketing Authorization	**Product Marketing Authorization**	
Product Name as Appeared on Marketing Authorization or Exemption	☐ No Update	Product Name as Appeared on Marketing Authorization or Exemption
STN-PD#	☐ No Update	STN-PD#
If No STN-PD #, Provide Reason	☐ No Update	If No STN-PD #, Provide Reason
Submitter Name	☐ No Update	Submitter Name
Applicant Name	☐ No Update	Applicant Name

4. Have you ceased manufacturing, but the remaining product is still being distributed by third parties? *(optional)*

☐ Yes *(provide information below)*

- Distributor Name: _____
- Distributor FEI #: _____
- Distributor Address: _____

☐ No

SECTION X – UPDATES TO MATERIAL FILE INFORMATION

Instructions for Section X

Provide information below on the type of change (i.e., adding new material file, updating existing material file details or association, updating date of dissemination, etc.)

1. Have there been any changes to the Material Files since the last submission?*

☐ Yes – *(proceed below to identify changes and provide updated information)*

☐ No – *(skip to Section XI – Certification Statement)*

2. Select the Material File updates needed *(select all that are applicable)**

☐ Adding new Material File to existing product

☐ Updating Material File for existing product

☐ Removing and/or replacing Material File for existing product

☐ Adding new Material File for new product

☐ Need to update Product – Material File association

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

Fields Impacted*

Previous Value on Last Submission	Updated Value for Current Submission	
Material File Identifiers	**Material File Identifiers**	
Material File Name	☐ No Update	Material File Name
Unique ID or Internal ID Number	☐ No Update	Unique ID or Internal ID Number
Date Material File First Disseminated *(mm/dd/yyyy)*	☐ No Update	Date Material File First Disseminated *(mm/dd/yyyy)*
Material File Information	**Material File Information**	
Material File Title	☐ No Update	Material File Title
Material File Description	☐ No Update	Material File Description
Material File Category	☐ No Update	Material File Category
Material File Type	☐ No Update	Material File Type
URL (if digital, social media, or website)	☐ No Update	URL (if digital, social media, or website)
Location of Labeling	☐ No Update	Location of Labeling

Previous Value on Last Submission		Updated Value for Current Submission	
Submitting a package label plan? ☐ Yes ☐ No		☐ No Update	Submitting a package label plan? ☐ Yes ☐ No
What variables are captured in the product variation index?		☐ No Update	What variables are captured in the product variation index?
Additional Material File Properties		☐ No Update	Additional Material File Properties
Associated Product Identifiers		**Associated Product Identifiers**	
Product Name		☐ No Update	Product Name
Universal Product Code (UPC)		☐ No Update	Universal Product Code (UPC)
Alternative Industry Product Identication Number and Type		☐ No Update	Alternative Industry Product Identication Number and Type

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***

Warning: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.

Identity of the Signatory*:

☐ Owner (listed in Section IV, Part B)

☐ Operator (listed in Section IV, Part C)

☐ Authorized Representative (listed in Section III, A or B)

1. Signature and Date *(mm/dd/yyyy)**

2. Typed Name and Title*

Appendix A: Terminology

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. **Authorized Representative:** Authorized representative or Authorized agent (for a foreign applicant), who can provide information related to registration and listing of the subject tobacco product manufacturer including the name, address, and contact information (including email address).
2. **Commercial Distribution:** Commercial distribution means any distribution of a tobacco product, whether domestic or imported, to consumers or to any 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 personal consumption or resale. “Commercial distribution” does not include the handling or transfer of a tobacco product from one consumer to another for personal consumption.
3. **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.
4. **Contract Manufacturer:** Manufactures a finished tobacco product to another establishment’s specifications.
5. **Domestic Establishment:** The term “domestic establishment” means an establishment in any State or Territory or possession of the United States.
6. **Electronic Nicotine Delivery System (ENDS):** Refers to an electronic device that delivers e-liquid (liquid nicotine combined with colorings, flavorings, and/or other ingredients such as propylene glycol (PG) and vegetable glycerin (VG)) in aerosol form into the mouth and lungs when inhaled, serving as an aerosolizing apparatus. The term may refer to vapes, vape pens, personal vaporizers, cigalikes, e-pens, e-hookahs, e-cigars, e-pipes, and e-cigarettes.
7. **Establishment:** The term “establishment” means a place of business under one ownership at one general physical location. A single building may house more than one distinct establishment if the establishments are under separate ownership.
8. **Finished Tobacco Product:** The term “finished tobacco product” means a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.
9. **Labeling:** The term “labeling,” based on section 201(m) of the FD&C Act (21 U.S.C. 321(m)), means all labels and other written, printed, or graphic matter (1) upon any tobacco product or any of its containers or wrappers, or (2) accompanying such tobacco product.
10. **Manufacturing:** The term “manufacturing” means the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package (section 905(a)(1) of the FD&C Act). This term includes the activities of reconstituting and blending tobacco leaf; testing for quality control and product release; and applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. This term excludes the activities of de-stemming, drying, or packing tobacco leaf; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaf with nothing other than potable water in the form of steam or mist.
11. **Material File:** For any listed tobacco product subject to section 905(i)(1)(A) of the FD&C Act, a material file includes a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product. For any listed tobacco product subject to section 905(i)(1)(B) of the FD&C Act, a material file includes a copy of all consumer information and other labeling for such tobacco product and a representative sampling of advertisements for such tobacco product.
12. **Contract Manufacturer:** Manufactures a finished tobacco product to another establishment's specifications.
13. **Domestic Establishment:** The term “domestic establishment” means an establishment in any State or Territory or possession of the United States.

14. **Non-Tobacco Nicotine (NTN):** The nicotine in the tobacco product is not made or derived from tobacco, such as synthetic nicotine.
15. **Operator:** The term “operator” means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) who has management authority over an establishment.
16. **Owner:** The term “owner” means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) who has an ownership interest in an establishment.
17. **Pouch:** The term "pouch" means a permeable pouch, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.
18. **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.
19. **Registrant:** FDA defines “registrant” as any person that registers a tobacco manufacturing facility and submits a product list for tobacco products commercially marketed in the United States.
20. **Retailer:** The term “retailer” means 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.
21. **Submission Tracking Number (STN):** The number that FDA assigns to submissions that are received from an applicant, such as a PMTA, supplemental PMTA, SE reports, exemption requests, MRTPAs, and submissions related to investigational tobacco products.
22. **Tobacco-Derived Nicotine (TDN):** The nicotine in the tobacco product is derived from tobacco.
23. **Tobacco Product:** The term “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).” This term does not include an article that is a drug, a device, a combination product, or a food if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine, as defined in the act (section 201(rr) of the FD&C Act (21 U.S.C. 321 (rr); as amended by section 111(a) of the Consolidated Appropriations Act, 2022 (Pub. L. 117-103)).

Appendix B: Statutory Requirements

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, a tobacco product (1) 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); and (2) does not mean an article that is a drug defined under section 201(g)(1) of the FD&C Act, a device defined under section 201(h) of the FD&C Act, or a combination product described in section 503(g) of the FD&C Act, or a food under section 201(f) of the FD&C Act if it 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(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.