DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

ALTERNATIVE TEST METHOD NOTIFICATION

Form Approved: OMB No. 0910-XXXX
Expiration Date: xx/xx/20xx
(See page 6 for PRA Statement)

Please type. An item followed by an asterisk (*) denotes a required field.

SECTION I - SUBMITTER IDENTIFICATION

Submission Date* *(mm/dd/yyyy)*	Submitter Type *(Check one)** ☐ Manufacturer ☐ Importer *(Complete Section II)*

Company Name*

Company Headquarters D&B D-U-N-S ® Number	Company Headquarters FDA-assigned Facility Establishment Identifier (FEI) Number

Address*	City*

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

Authorized Representative *(Responsible official authorized to represent the submitter)*

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

Professional Suffix*(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name* ☐ Check here if same as submitter company name above, and skip to Address.

Address* ☐ Check here if same as above, and skip to Section II.	City*

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

SECTION II - MANUFACTURER OF IMPORTED PRODUCTS
Required only for importers

Company Name*

Company Headquarters D&B D-U-N-S ® Number	Company Headquarters FDA-assigned Facility Establishment Identifier (FEI) Number

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

U.S. Agent *(Responsible official authorized to represent the foreign manufacturer)*

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

Professional Suffix*(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name* ☐ Check here if same as manufacturer company name above, and skip to Address.

Address* ☐ Check here if same as above, and skip to Section III.		City*
State, Province or Territory*	Country*	ZIP or Postal Code*

SECTION III - SUBMISSION TYPE

1. Purpose of Submission*

To notify FDA of an alternative test method to be implemented in lieu of the FDA standard test method

2. Submission Type* *(Select one)*

☐ Initial Submission of Notification *(Complete Section IV, and skip Section V)*

☐ Amendment to Original Submission *(Skip Section IV, and complete Section V)*

SECTION IV - INITIAL SUBMISSION OF NOTIFICATION

If the submission is an initial submission of Notification, complete parts A-E.

Part A: Identification of Alternative Test Method* *(Enter below; It should uniquely identify the procedure & reflect its originating organization, procedure name & version date.)*

Part B: Identification of Product Category and Sub-Category* *(Select all that apply)*

Please select either or both (component and/or co-packaged), as applicable, then select all that apply futher below.

- If product is a component, check here ☐
- If product is co-packaged, check here ☐

☐ **Cigarette**
- ☐ Combusted, Filtered
- ☐ Combusted, Non-Filtered
- ☐ Non-Combusted
- ☐ Combusted, Other *(Specify below)*

_____

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

_____

☐ **Electronic Nicotine Delivery System (ENDS)**
- ☐ Open E-Liquid
- ☐ Closed E-Liquid
- ☐ Open E-Cigarette
- ☐ Closed E-Cigarette
- ☐ ENDS, Other *(Specify below)*

_____

☐ **Pipe Tobacco Products**
- ☐ Pipe
- ☐ Pipe Tobacco Filler
- ☐ Pipe, Other *(Specify below)*

_____

☐ **Roll-Your-Own Tobacco Products**
- ☐ Roll-Your-Own Tobacco Filler
- ☐ Rolling Paper
- ☐ Filtered Cigarette Tube
- ☐ Non-Filtered Cigarette Tube
- ☐ Filter
- ☐ Paper Tip
- ☐ Roll-Your-Own Co-package
- ☐ Roll-Your-Own, Other *(Specify below)*

_____

☐ **Smokeless Tobacco Products**
- ☐ Loose Moist Snuff
- ☐ Portioned Moist Snuff
- ☐ Loose Snus
- ☐ Portioned Snus
- ☐ Loose Dry Snuff
- ☐ Dissolvable
- ☐ Loose Chewing Tobacco
- ☐ Portioned Chewing Tobacco
- ☐ Smokeless, Other *(Specify below)*

_____

☐ **Waterpipe Tobacco Products**
- ☐ Waterpipe
- ☐ Waterpipe Tobacco Filler
- ☐ Waterpipe Heat Source
- ☐ Waterpipe, Other *(Specify below)*

_____

Part C: Testing Facility ID

Establishment Name*

Establishment FDA-assigned Facility Establishment Identifier (FEI) Number

Address* *(i.e., Physical location)*	City*	
State, Province or Territory*	Country*	ZIP or Postal Code*

Accreditation Organization Name

Accredited Lab Number	Expiration Date *(mm/dd/yyyy)*

Authorized Representative *(Responsible official authorized to represent the Testing Facility)*

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

Professional Suffix*(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name ☐ Check here if same as establishment name above, and skip to Address.

Address ☐ Check here if same as establishment address, and skip to Part D.	City

State, Province or Territory	Country	ZIP or Postal Code

Part D: Summary of Test Method Validation Report *(Check the box if you are including this report.)*

☐ Summary of Test Method Validation Report is included.

Part E: Analytical Test Method* *(Include attachments)*

The proposed alternative analytical test method shall at a minimum include the following information:

- Full test data including the following for all testing performed during method validation:
  - Detailed description of method (protocol)
  - Complete data sets for each product tested
  - Accuracy
  - Precision
  - Robustness
  - Limit of detection (LOD)
  - Complete datasets for reference products (if applicable)
  - A summary of the results for all testing performed
  - Recovery
  - Linearity
  - Limit of quantitation (LOQ)
  - Range
  - Specificity
- Analytical procedures (including details regarding extraction, derivatization, and/or any other procedures used during sample preparation), validation protocols, validation reports, system suitability protocols, and any other pertinent information for that alternative analytical test method
- Representative chromatograms and calibration curves shall be provided in an image file format (e.g., JPEG, GIF, TIFF).

SECTION V - AMENDMENT TO ORIGINAL SUBMISSION

If the submission is an amendment to an original submission, complete parts A and B.

Part A: Original FDA Submission Tracking Number (STN)

FDA Submission Tracking Number (STN) of the original submission: _____

Part B: Identification of the Amendment Purpose *(Check all that apply)*

☐ 1. Response to an FDA Information Request dated: _____ *(mm/dd/yyyy)*

Provide submission description below.

☐ 2. Minor Updates *(e.g., typographical corrections, change in contact)*

Note: Changes in analyte,procedure, instrument/parameter, material/reagent, or lab) require submitting as a new Notification.

Provide submission description below.

☐ 3. Request to Withdraw Initial Submission of Notification

SECTION VI – CONFIRMATION STATEMENT

I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

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

☐ **Agree**

Signature of Authorized Representative or U.S. Agent for Foreign Manufacturer	Typed Name and Title	Date

Contact Information of Authorized Representative or U.S. Agent for Foreign Manufacturer

☐ If your point of contact information is the same as submitter in Section I, check here and skip to Company Name.

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g., Jr., III)*

Professional Suffix*(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name ☐ Check here if same as submitter, and skip to Address.

Address ☐ Check here if same as submitter, and skip address items.	City

State, Province or Territory	Country	ZIP or Postal Code

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 20 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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