DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PREMARKET TOBACCO PRODUCT APPLICATION AMENDMENT AND GENERAL CORRESPONDENCE SUBMISSION

Form Approved: OMB Control No. 0910-xxxx
Expiration Date: xx/xx/xxxx
See PRA Statement on page X.

SECTION I - APPLICANT IDENTIFICATION

1. Name of Applicant	2. Date of Submission

3. Name of Manufacturer *(If different from applicant)*

4. FDA Establishment Identifier (FEI) *(If applicable)*	5. D&B DUNS Number of Headquarters *(If applicable)*

6. Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)		City	State/Province/Region
Address 2 (Apt, Suite, Unit, Bldg., Floor, etc.)		Country	ZIP or Postal Code
Telephone	FAX	Email	

SECTION II - Submission Information and Contents

Type of Submission *(Select appropriate category, then you must fill in and/or select applicable follow-on items.)*

☐ General Correspondence

- ☐ Change in Manufacturer, Authorized Representative, U.S. Agent or Alternate Point of Contact Information
- ☐ Change in Ownership
- ☐ Request to Withdraw the PMTA [PM########]
- ☐ Change in Manufacturing/Packaging/ Sterilization Site Information
- ☐ Adverse Experience Report
- ☐ Periodic Report *(e.g. Annual Report)*
- ☐ Other (Specify below)

☐ Amendment *[Include submission tracking Number (PM########)]*

Scientific Content included in the amendment: *(See instructions for use for description*)

- ☐ General Information
- ☐ Descriptive Information
- ☐ Product Samples
- ☐ Statement of Compliance with 21 CFR part 25
- ☐ Summary
- ☐ Product Formulation
- ☐ Manufacturing
- ☐ Literature Search
- ☐ Organized References
- ☐ Health Risk Investigations
- ☐ Study Reports
- ☐ Response to Advice/Information Request
- ☐ Other (Specify below)

SECTION III - ADDITION OR REMOVAL OF AUTHORIZED REPRESENTATIVE, U.S. AGENT, OR ALTERNATE POINT OF CONTACT

Addition or removal of Authorized Representative Select one: ☐ Add ☐ Remove Effective date

7. Name of Authorized Representative

8. Authorized Representative Address and Contact Information

Primary Address (Street Address, P.O. Box)		City	State/Province/Region
Address 2 (Apt, Suite, Unit, Bldg., Floor, etc.)		Country	ZIP or Postal Code
Telephone	FAX	Email	

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Addition or Removal of U.S. Agent	Select one: ☐ Add ☐ Remove	Effective date

9. Name of U.S. Agent

10. U.S. Agent Address and Contact Information

Primary Address (Street Address, P.O. Box)		City	State/Province/Region
Address 2 (Apt, Suite, Unit, Bldg., Floor, etc.)		Country	ZIP or Postal Code
Telephone	FAX	Email	

Addition or Removal of Alternate Point of Contact	Select one: ☐ Add ☐ Remove	Effective date

11. Name of Alternate Point of Contact

12. Alternate Point of Contact Address and Contact Information

Primary Address (Street Address, P.O. Box)		City	State/Province/Region
Address 2 (Apt, Suite, Unit, Bldg., Floor, etc.)		Country	ZIP or Postal Code
Telephone	FAX	Email	

SECTION IV - Change In Ownership

Effective Date of Ownership Change (mm/dd/yyyy)

Current Owner Information

Manufacturer Name

FDA Establishment Identifier (FEI)		D&B DUNS Number of Headquarters	
Primary Address (Street Address, P.O. Box)		City	State/Province/Region
Address 2 (Apt, Suite, Unit, Bldg., Floor, etc.)		Country	ZIP or Postal Code
Telephone	FAX	Email	

New Owner Information

Manufacturer Name

FDA Establishment Identifier (FEI)		D&B DUNS Number of Headquarters	
Primary Address (Street Address, P.O. Box)		City	State/Province/Region
Address 2 (Apt, Suite, Unit, Bldg., Floor, etc.)		Country	ZIP or Postal Code
Telephone	FAX	Email	

Transfer Request

Would you be transferring all submissions related to an entire brand to the new owner? ☐ Yes ☐ No

If yes, identify the brand(s) for all submissions you would be transferring

List of submission tracking numbers that would be transferred

Have you submitted a signed notice to FDA stating that all rights to the PMTA have been transferred to the new owner?

Select one: ☐ Yes ☐ No

Have you submitted a signed noticed to FDA with the new applicant's commitment to agreements, promises and conditions made by the former applicant and contained in the PMTA?

Select one: ☐ Yes ☐ No

SECTION V - ADDITION OR REMOVAL OF MANUFACTURING/PACKAGING/STERILIZATION SITES

Addition or removal of Manufacturing/Packaging/Sterilization sites: Select one: ☐ Add ☐ Remove

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer
☐ Contract Manufacturer ☐ Repacker/Relabeler

The Manufacturing/Packaging/Sterilization Site is ready for inspection Select one: ☐ Yes ☐ No

Company/Institution Name		Establishment Registration Number	
Division Name		Phone Number *(Including area code)*	
Street Address		FAX Number *(Including area code)*	
City	State/Province	ZIP Code	Country
Contact Name		Contact Title	

Email

SECTION VI - CERTIFICATION STATEMENT

Select one of the following, then sign after entering your name in the statement.

I am signing below as a/an: ☐ Applicant ☐ Authorized Representative ☐ U.S. Agent

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

Signature	Date

APPENDIX
INSTRUCTIONS FOR USE

This form and the instructions for use are solely intended to provide the applicant an organized format to supply information required for a Premarket Tobacco Product Application (PMTA) Amendment and General Correspondence Submission.

Section I - Applicant Identification

- Provide applicant name (means any person that submits a premarket tobacco product application to receive a marketing order for a new tobacco product
- Provide date submission was submitted
- Provide manufacturer name (if different from applicant)
- Provide FDA Establishment identifier (FEI) (if applicable)
- Provide D&B DUNS Number of Headquarters (if applicable)
- Provide applicant address and contact information

Section II - Submission Information and Contents

- Select type of submission: check box if the submission is a general correspondence or if the submission is an amendment
- Check the appropriate box if:
  - there is a change in manufacturer, authorized representative, U.S. Agent or alternate point of contact information
  - there is a change in ownership information 21 CFR § 1114.13
  - you would like to withdraw a PMTA, include PM# 21 CFR § 1114.11
  - you would like to inactivate a PMTA, include PM# 21 CFR § 1114.43
  - you would like to reactivate a PMTA, include PM# 21 CFR § 1114.43
  - the submission is to respond to an Advice/Information Request
  - there is a change in Manufacturing/Packaging/Sterilization Site Information 21 CFR § 1114.7(j)
  - the submission includes an Adverse Experience Report
  - the submission includes a Periodic Report 21 CFR § 1114.41(a)(1)
- Select the type of scientific content included in the submission:
  - General information 21 CFR § 1114.7(c)(e.g., product name, product category, subcategory and product properties)
  - Descriptive information 21 CFR § 1114.7(d)
  - Product samples 21 CFR § 1114.7(e)
    - FDA generally expects that product samples will be a required part of a PMTA. There may be situations in which sample submission may not be necessary, including, for example, some PMTAs that are resubmitted for the same product after a no marketing order and PMTAs submitted for modifications to an authorized product where the modifications do not require new samples to be reviewed as part of the PMTA evaluation process. Presubmission meetings with the FDA may help provide additional information about whether product samples will need to be included in a PMTA; however, in most situations, FDA will only be able to determine the need for product samples after a PMTA is accepted for review.
  - Statement of compliance with 21 CFR part 25 (e.g. Environmental Assessment) 21 CFR § 1114.7(g)
  - Summary 21 CFR §1114.7(h)
  - Product formulation 21 CFR § 111.7(i) (e.g., components, ingredients, additives, properties, and principles of operations)
  - Manufacturing 21 CFR 111.4.7(j) (e.g., methods, facilities, controls)
  - Literature Search
    - A literature search is a search of available documents that includes: 1) clear search objectives 2) a description of methodologies used in the search in detail 3) an identification of relevant documents 4) a formal or informal evaluation of study quality 5) an analysis of study findings and 5) a bibliography of referenced publications.
  - Organized References used to compile information in the submission
  - Health Risk Investigations
    - Examples of health risk investigations include but not limited to; Toxicological Risk Evaluation, Health Impact (e.g., use behavior, health risk), Tobacco Product Perception and Intention Studies

- Study Report(s) - examples of documents include:
  - Study protocol
  - Statistical analysis plan
    i. Study report
    ii. Statistical software programming code
    iii. Study instruments (e.g. surveys/questionnaires)
    iv. Informed consent form

- Case Report Forms (as appropriate)
  In general Case Report Forms (CRFs) from clinical studies are not needed for filing a PMTA. However, FDA will require for filing the CFRs from clinical studies that have been made to show the health risks of the PMTA product and whether such product presents less risk than other tobacco products where the CRF: 1) relates to participant deaths, other serious and unexpected adverse experiences, or participant discontinuation (including withdrawals) **AND** 2) where the study participant was exposed to the tobacco product(s) which is/are the subject of the PMTA(s) or to a similar/related product that the applicant is using to show that the PMTA product meets the standard for marketing authorization under section 910. Additional information may be requested on a case-by-case basis during FDA review. FDA expects all CRFs would be available for review during Agency inspections of clinical and/or nonclinical study sites.

- Analyzable Data sets
  In general raw data such as raw chromatograms/spectra/mass spectra arising from analytical chemistry testing and raw (meaning no integration of the data) output from high-throughput (e.g., genomic) studies are not needed for filing a PMTA. **Line data/ analyzable datasets** that are representative chromatograms/spectra/mass spectra that demonstrate the adequacy of separations/ specificity, standard solution, and sample solutions **should be included**. The line data/analyzable data sets may be used to replicate findings or conduct alternative analyses of the underlying data. Additional information may be requested on a case-by-case basis during FDA review. FDA expects all raw data would be available for review during Agency inspection of clinical and/or nonclinical study sites.

- Other

Section III - Additional or Removal of Authorized Representative, U.S. Agent or Alternate Point of Contact

- Select add or remove if you are adding or removing the Authorized Representative, U.S. Agent or Alternate Point of Contact
- Provide all demographic information for the Authorized Representative, U.S. Agent or Alternate Point of Contact

Section IV - Change in Ownership

- Provide effective date of the change in ownership 21 CFR § 1114.13
- Complete all manufacturer demographic information 21 CFR § 1114.7(j)
- Identify if you are transferring all submissions related to a brand or brands
- List all STNs subject to the change in ownership 21 CFR § 1114.13(a)
- Select yes or no if you have submitted a signed notice to FDA stating that all rights to the PMTA have been transferred to the new owner 21 CFR § 1114.13(a)
- Select yes or no if you have submitted a signed notice to FDA with the new applicant's commitment to agreements, promises and conditions made by the former applicant and contained in the PMTA 21 CFR § 1114.13(b)(1)

Section V - Manufacturing/Packaging/Sterilization Sites Relating to a Submission

- Select add or remove if you are adding or removing a Manufacturing/Packaging/Sterilization Site
- Complete all manufacturing demographic information 21 CFR § 1114.7(j)

Section VI - Certification Statement

- Select the checkbox Applicant, Authorized Agent or U.S. Agent and sign the certification statement

We remind you that all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter or mailed to:

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

We are unable to accept regulatory submissions by electronic mail.

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

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

The burden time for this collection of information is estimated to average 5 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following email address:

For PRA questions
PRAStaff@fda.hhs.gov

OMB Statement: *"An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*