DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TOBACCO AMENDMENT AND GENERAL CORRESPONDENCE REPORT

Form Approved: OMB No. xxxx-xxxx
Expiration Date: xx/xx/201x
(See Burden Statement on last page.)

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 (the FD&C Act).

STATUTORY REQUIREMENTS

Section 910(a)(1) of the FD&C Act – Defines a new tobacco product as "(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007."

Section 910(a)(2) of the FD&C Act – Premarket review required for new tobacco products. There are three pathways to achieve marketing authorization. Substantial Equivalence is one of the three pathways.

Section 910(a)(3) of the FD&C Act – "Substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product ''(i) has the same characteristics as the predicate tobacco product; or (ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health."

Section 905(j)(1)(A)(i) of the FD&C Act – Includes the time frame and basis for submission of a Substantial Equivalence Report (SE Report).

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Please type. An item followed by an asterisk (*) denotes a required field. Please note that some subordinate items not marked with an asterisk will be required under certain conditions, depending on the written prompt for preceding required item.

SECTION I – APPLICANT IDENTIFICATION

Applicant Name

FDA Establishment Identifier (FEI)	D&B DUNS Number of Headquarters

Applicant Street Address *(Physical location)*	Building Number and Street*	
Room, Suite, Office Mail Code, etc. *(If applicable)*	City*	
State, Province, or Territory*	Country*	Postal Code*

SECTION II – SUBMISSION INFORMATION AND CONTENTS

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

☐ Amendment *(If selected, fill in below, per prompts.)*

For Amendments fill in information below.

Amending Submission Tracking Number

_____

Date of FDA Letter *(If applicable)(mm/dd/yyyy)*

_____

Response to Information Request *(Select one)*:

- ☐ Advice/Information Request
- ☐ Preliminary Finding
- ☐ Grandfathered Evidence *(Complete Section IV)*
- ☐ Other *(Describe in Submission Summary)*

☐ General Correspondence *(If selected, fill in below, per prompts.)*

For General Correspondence select one of the following.

- ☐ Change in Ownership Request *(Complete Section III)*
- ☐ Request to Withdraw
- ☐ Correction *(Describe in Submission Summary)*
- ☐ Applicant Address or Information Change
- ☐ Addition or Removal of a Point of Contact (*Complete section V)*
- ☐ Other *(Describe in Submission Summary)*

Submission Summary *(Required if instructed to "Describe" by a previous prompt.)*

SECTION III – REQUEST FOR CHANGE IN OWNERSHIP

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

Current Ownership Information

Manufacturer Name

FDA Establishment Identifier (FEI)	D&B DUNS Number of Headquarters

Current Owner Street Address *(Physical location)*	Building Number and Street	
Room, Suite, Office Mail Code, etc. *(If applicable)*	City	
State, Province, or Territory	Country	Postal Code

Proposed New Owner Information

Manufacturer Name

FDA Establishment Identifier (FEI)	D&B DUNS Number of Headquarters

Proposed New Owner Street Address *(Physical location)*	Building Number and Street	
Room, Suite, Office Mail Code, etc. *(If applicable)*	City	
State, Province, or Territory	Country	Postal Code

Transfer Requests

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:

SECTION IV – GRANDFATHERED PRODUCT EVIDENCE

(Complete only if the predicate has not been previously reviewed by CTP.)

Subsection A. Evidence of Commercial Marketing As of 2/15/2007

(For additional evidentiary items, attach sheet(s) following the format below.)

Type of Evidence *(e.g., Invoice)*	Date of Evidence
Evidence Identifier *(e.g., Invoice Number.)*	Commercial Information *(e.g., UPC Code, Product Description, Item Number)*

Commercially Marketed Business Address *(Physical location)*	Building Number and Street	
Room, Suite, Office Mail Code, etc. *(If applicable)*	City	
State, Province, or Territory	Country	Postal Code

Subsection B. Test Market Statement

I, _____ confirm that the predicate tobacco product associated with this
*Authorized Representative**

Substantial Equivalence Submission for _____
Name of Tobacco Product

was commercially marketed other than for test marketing in the United States as of February 15, 2007.

* *Authorized representative should be an individual who has knowledge of the test marketing status of the tobacco product and who has authority to make such a statement.*	Signature

SECTION V – ADDITION OR REMOVAL OF POINT OF CONTACT

Select one: ☐ Add ☐ Remove

Company Name

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

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

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

Telephone *(Include Country Code if applicable)*	FAX

Point of Contact Mailing Address	Building Number and Street
Room, Suite, Office Mail Code, etc. *(If applicable)*	City
State, Province, or Territory	Country / Postal Code

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: ☐ Authorized Representative ☐ U.S. Agent

I, _____ certify that the data in the submission have been reviewed and are
Name

true and accurate, and that the applicant is not aware that any material fact has been omitted.

	Signature

INSTRUCTIONS

Section I – Applicant Identification

Complete all demographic information.

Section II – Submission Information and Contents

- Indicate Amendment or General Correspondence.
- If Amendment, provide reference or related STN and identify the submission contents.
- If General Correspondence, identify submission contents.

Section III – Request for Change in Ownership

- Provide the effective date of the change in ownership.
- Complete all manufacturer demographic information.
- Identify if you are transferring all submissions related to a brand or brands.
- List all STNs subject to the change in ownership.

Section IV – Grandfathered Product Evidence

Subsection A – Evidence Of Commercial Marketing As of 2/15/2007

Fill out Subsection A only if you are requesting grandfathered status with this application for your predicate tobacco product. Repeat subsection A for additional evidentiary support.

- Type of Evidence: Provide brief description of what is submitted, e.g., invoice, bill of lading, etc.
- Date of Evidence: Provide the date on the evidence.
- Evidence Identifier: Provide an identifying number or code for the evidence type, e.g., invoice number.
- Commercial Information: Provide UPC Code, SKU number, or other identifier, if applicable.
- Tobacco Product Quantity: Provide the quantity of the product as identified in the type of evidence.
- Business Address where product was commercially marketed: Provide the address of the establishment subject to the evidence provided, e.g., the location of the establishment that the product was commercially sold on February 15, 2007.

Subsection B – Test Market Statement

Complete all fields and Sign to affirm that the predicate product was commercially marketed other than for test marketing in the United States as of February 15, 2007.

Section V – Addition or Removal of Point of Contact

- Select if you are adding or removing a Point of Contact.
- Provide all demographic information for the Point of Contact you are adding or removing.

Section VI – Certification Statement

- Select if you are acting as an authorized representative or U.S. Agent.
- Insert your name and sign where indicated.