DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

REGISTRATION AND LISTING FOR OWNERS AND OPERATORS OF DOMESTIC TOBACCO PRODUCT ESTABLISHMENTS

Form Approved: OMB No. 0910-0650
Expiration Date: 10/31/2015
(See page 11 for PRA Statement)

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 act) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Complete the following question and answer form to register your establishment and submit your product listing to FDA's Center for Tobacco Products. For additional information on the legislation and guidance document, access the web links provided on page 11.

STATUTORY REQUIREMENTS

All owners and operators must fulfill the requirements for section 905 of the act, as detailed below. *In order to reduce redundant submissions, FDA strongly encourages owners to register and submit product listing information for themselves and on behalf of their operators*.

Section 905(b) of the act requires that "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 the Secretary the name, places of business, and all such establishments of that person."

Section 905(i)(1) of the act requires that all registrants "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 labeling.

Section 905(i)(3) of the act requires that certain changes in the product list be submitted biannually, once during June and once during December.

DEFINITIONS

FDA intends to use the following definitions in implementing the registration and product listing requirements of section 905 of the act.

1. **Commercial Distribution:** The term "commercial distribution" includes any distribution of a tobacco product to consumers or to another person for future manufacturing through sale or otherwise. As examples, it includes the distribution of a tobacco product as a promotional sample and the delivery of a tobacco product to another manufacturer for further processing via contract without a change in the formal ownership of the product. Commercial distribution does not include internal or interplant transfer of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company and it does not include providing a tobacco product for product testing in cases where such products are not made available for consumption or resale.

2. **Domestic Establishment:** The term "domestic establishment" means an establishment in any State or Territory or possession of the United States.

3. **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.

(Continued on next page)

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4. **Labeling:** The term "labeling," based on section 201(m) of the 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.

5. **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 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.

6. **Operator:** The term "operator" means a person, as defined in section 201(e) of the act (21 U.S.C. 321(e)) who has management authority over an establishment.

7. **Owner:** The term "owner" means a person, as defined in section 201(e) of the act (21 U.S.C. 321(e)) who has an ownership interest in an establishment.

8. **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.

9. **Tobacco Product:** The term "tobacco product" means "any product made or derived from tobacco 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)" (section 201(rr) of the act (21 U.S.C. 321 (rr)). This term does not include an article that is a drug, a device, or a combination product as defined in the act (section 201(rr) of the act (21 U.S.C. 321 (rr)). Thus, the term is not limited to products containing tobacco, but also includes components, parts and accessories of tobacco products, whether they are sold for further manufacturing or are ready for consumer use. For example, tobacco papers and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

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See page 15 for Instructions

Form Approved: OMB No. 0910-0650
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Please type. An item followed by an asterisk (*) denotes a required field.

Check one of the following.* For updates, FDA requests that you also provide your FEI number or the DUNS Number used in your original submission.	☐ New Submission and Product Listing *(per 905(b) and 905(i)(1))*	☐ Update to a Registration *(per 905(b)) (previously submitted to FDA)*	☐ Update to a Product List *(per 905(i)(3))(previously submitted to FDA)*
	Identification Number *(If update)*		

SECTION I - IDENTIFICATION

Please check the appropriate boxes.* *(Note that owners and operators may register on behalf of the other party.)*

REGISTRATION STATUS

1 ☐ Owner registering alone *(Complete all sections EXCEPT IIIA and IIIB)*

2 ☐ Owner registering on behalf of operator *(Complete all sections)*

3 ☐ Owner who is also operator of all establishments *(Complete all sections)*

4 ☐ Operator registering alone *(Complete all sections EXCEPT IIA and IIB)*

5 ☐ Operator registering on behalf of owner *(Complete all sections)*

SECTION IIA - REGISTRATION
Owner Information

Owner Name (Name of the Corporation/Partnership or Individual Owner)*

Address*	City*

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

Owner Headquarters D&B DUNS Number:

Owner Point of Contact

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

First/Given Name	Middle Name	Last Name

Position Title

Email Address

Telephone *(Include Country Code if applicable)*	FAX

SECTION IIB - REGISTRATION
Owner Business Structure

Select the type of business structure (Sole Proprietorship, Partnership, or Corporation) and provide indicated information.* *(Continuation sheets may be used if necessary.)*

☐ **Sole Proprietorship** *(Enter owner name)*

☐ **Partnership** *(Enter name of each partner)*

1.

2.

3.

4.

5.

6.

☐ **Corporation** *(Enter the name of each corporate officer and director)*

1.

2.

3.

4.

5.

6.

Identify State of incorporation.	Please describe further. *(If applicable, give name of country if incorporation made outside U.S.)*

If the owner does business by any other name, please list all such names.

1.

2.

3.

4.

SECTION IIIA - REGISTRATION
Operator Information

Multiple copies of this page may be submitted if you are registering on behalf of multiple operators.

Operator Name*

Address*

City*	State*	ZIP Code*

Operator D&B DUNS Number:

Operator Point of Contact

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

First/Given Name	Middle Name	Last Name

Position Title

Email Address

Telephone *(Include Country Code if applicable)*	FAX

SECTION IIIB - REGISTRATION
Operator Business Structure

Select the type of business structure (Sole Proprietorship, Partnership, or Corporation) and provide indicated information.* *(Continuation sheets may be used if necessary. Multiple copies of this page may be submitted if you are registering on behalf of multiple operators.)*

☐ **Sole Proprietorship** *(Enter operator name)*

☐ **Partnership** *(Enter name of each partner)*

1.

2.

3.

4.

5.

6.

☐ **Corporation** *(Enter the name of each corporate officer and director)*

1.

2.

3.

4.

5.

6.

Identify State of incorporation.	Please describe further. *(If applicable, give name of country if incorporation made outside U.S.)*

If the operator does business by any other name, please list all such names.

1.

2.

3.

4.

SECTION IV - REGISTRATION
Establishment Information

Enter contact and registration information for each establishment being registered. *(Multiple copies of this page may be submitted.)*

Establishment Name*

Address*

City*	State*	ZIP Code*

Establishment D&B DUNS Number:

Operation *(Check all that apply)*

- ☐ Blending
- ☐ Manufacturing
- ☐ Reconstituting Tobacco
- ☐ Packaging
- ☐ Labeling
- ☐ Saucing (or casing)
- ☐ Storing
- ☐ Testing
- ☐ Other *(Specify)*: _____

Establishment Point of Contact

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

First/Given Name	Middle Name	Last Name

Position Title

Email Address

Telephone *(Include Country Code if applicable)*	FAX

SECTION V - PRODUCT LISTING

Section V should be completed for each product listed. *(Multiple copies of pages 8 and 9 may be submitted.)*

1. Product Name* *(i.e., brand/sub-brand or other commercial name used in commercial distribution - e.g., Acme Lights 100's or Acme Reconstituted Tobacco #202)*

2. Product Identification Number *(Must be provided if needed to uniquely identify the product)*

3. Type of Product Identification Number *(Check only one)*

- ☐ Item/Catalog Number
- ☐ SKU Number
- ☐ UPC Number

4. Intended Use of Product *(Check one)**

- ☐ Consumer Use *(Go to question 5)*
- ☐ Further Manufacturing Use *(Skip to question 6)*

5. Consumer Use Product Category *(Check applicable, then skip to question 7)**

- ☐ Cigarettes
- ☐ Chewing Tobacco
- ☐ Dissolvables
- ☐ Accessory Filters
- ☐ Roll-Your-Own Tobacco
- ☐ Roll-Your-Own Paper
- ☐ Roll-Your-Own Filters
- ☐ Other *(Specify)*: _____
- ☐ Dry Snuff
- ☐ Moist Snuff
- ☐ Snus

6. Further Manufacturing Use Product Category *(Check applicable)**

- ☐ Tobacco
- ☐ Paper
- ☐ Filters
- ☐ Pouch for Portioned Tobacco
- ☐ Additive
- ☐ Other *(Specify)*: _____

7. Flavor *(Check applicable)*

- ☐ Menthol
- ☐ None
- ☐ Other *(Specify)*: _____

8. If submission is an Update to a Product List *(per 905(i)(3)) (previously submitted to FDA) (Make applicable entries)*

If known, enter the FDA-assigned tracking number (e.g., TP########) for your tobacco product.

If your product has been introduced to market, discontinued or reintroduced since your last product listing, indicate the most recent change.*

Provide the appropriate date:*

9. **Advertising** *(A representative sampling of advertising may be required. Please see the guidance document, Section III.C.2. for additional details. Representative samples, appropriately identified, are to be submitted with this form. For each advertisement, we request that you provide the following optional information below. You may use Appendix A as a continuation sheet if needed.)*

9a. Type of Advertising Material *(e.g., magazine ad)*	9b. Title	9c. Unique ID or Internal ID Number	9d. Date First Disseminated *(mm/dd/yyyy)*

10. **Labeling*** *(All labeling, appropriately identified, is to be submitted with this form. For each item of labeling, we request that you provide the following optional information below. You may use Appendix B as a continuation sheet if needed.)*

10a. Universal Product Code(s) (UPC)

10b. Type of Labeling Material *(e.g., package label)*	10c. Title	10d. Unique ID or Internal ID Number	10e. Date First Disseminated *(mm/dd/yyyy)*

11. **Consumer Information** *(Consumer information may be required. Please see the guidance document, Section III. C.2. for additional details. All consumer information, appropriately identified, is to be submitted with this form. For each item, we request that you provide the following optional information below. You may use Appendix C as a continuation sheet if needed.)*

11a. Type of Consumer Information *(e.g., consumer brochure)*	11b. Title	11c. Unique ID or Internal ID Number	11d. Date First Disseminated *(mm/dd/yyyy)*

SECTION VI - CONFIRMATION 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 report changes to this information as required under section 905(i)(3) of the act.

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

☐ **Agree**

Signature of Responsible Person or Agent	Typed Name and Title	Date

Identity of the Signatory

- ☐ Owner *(Listed in section IIA)*
- ☐ Operator *(Listed in section IIIA)*
- ☐ Authorized Agent *(Complete section below)*

Authorized Agent Contact Information

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

First/Given Name	Middle Name	Last Name

Position Title

Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name

Address	City

State, Province or Territory	Country	ZIP or Postal Code

REFERENCES

Reference for the Tobacco Control Act:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm298595.htm

Reference for *Guidance on Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments*:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm

For regulatory questions 904 and 905 of act, email TobaccoIndustryQuestions@fda.hhs.gov. Regulatory Submissions can be mailed to:

Center for Tobacco Products
Document Control Center, Room 020J
9200 Corporate Boulevard
Rockville, MD 20850

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

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

The burden time for this collection of information is estimated to average 3.75 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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 control number."

APPENDIX A - ADVERTISING
Continuation Sheet

Enter information below for a representative sample of advertising. *(See Section V for details.)*

Product Name	Product Identification Number

Type of Advertising Material *(e.g., magazine ad)*	Title	Unique ID or Internal ID Number	Date First Disseminated *(mm/dd/yyyy)*

APPENDIX B - LABELING
Continuation Sheet

Enter labeling information below.* *(See Section V for details.)*

Product Name	Product Identification Number

Universal Product Code(s) (UPC):

Type of Labeling Material *(e.g., package label)*	Title	Unique ID or Internal ID Number	Date First Disseminated *(mm/dd/yyyy)*

APPENDIX C - CONSUMER INFORMATION
Continuation Sheet

Enter consumer information below. *(See Section V for details.)*

Product Name	Product Identication Number

Type of Consumer Information *(e.g., consumer brochure)*	Title	Unique ID or Internal ID Number	Date First Disseminated *(mm/dd/yyyy)*

INSTRUCTIONS

Section I

- If you check box 1, complete all sections except IIIA and IIIB.
- If you check box 2, complete all sections.
- If you check box 3, complete all sections.
- If you check box 4, complete all sections except IIA and IIB.
- If you check box 5, complete all sections.

Section IIA

Provide all required information for the Owner. FDA requests that you also provide a point of contact, to facilitate communication between the Owner and FDA. If an Operator is registering alone, the Operator may skip Sections IIA and IIB.

Section IIB

Owners must provide the specified details for their business structure. Only one business structure should be selected. If an Owner uses any trade names to conduct business other than the company name identified in Section IIA, FDA requests that such names be listed here.

Section IIIA

Provide all required information for the Operator. FDA requests that you also provide a point of contact, to facilitate communication between the Operator and FDA. Owners registering alone may skip Sections IIIA and IIIB. If you are an Owner or Operator registering on behalf of multiple Operators, you must submit a separate IIIA and IIIB for each Operator.

Section IIIB

Operators must provide the specified details for their business structure. Only one business structure should be selected. If an Operator uses any trade names to conduct business other than the company name identified in Section IIIA, FDA requests that such names be listed here.

Section IV

Provide all required information for each Establishment. FDA requests that you also provide a point of contact, to facilitate communication between the Establishment and FDA. The contact person for a given Establishment does not need to be the Operator, but should be an individual authorized to communicate with FDA. Owners and Operators must register and submit a separate Section IV for each Establishment they own or operate. If you are an Operator registering on behalf of an Owner, you must complete a separate Section IV for each Establishment owned by that Owner, even if you are not the Operator of all of the Establishments.

Section V

This section applies to each product manufactured by the registrant. If an Owner or Operator intends to list multiple products, multiple copies of Section V may be submitted. If additional space is needed for submission of advertising information, registrants may use Appendix A to identify additional items of advertising submitted per product. If additional space is needed for submission of labeling information, registrants may use Appendix B to identify additional items of labeling submitted per product. If additional space is needed for submission of consumer information, registrants may use Appendix C to identify additional items of consumer information submitted per product.

Section VI

Registration and listing information may be submitted only by an owner, operator, or authorized agent thereof. If an agent has been authorized to submit registration and listing information, FDA requests that contact information for that agent be entered in this section.