DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

LISTING OF INGREDIENTS IN TOBACCO PRODUCTS

Form Approved: OMB No. 0910-0650
Expiration Date: 1/31/2019
(See page 8 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 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.

STATUTORY REQUIREMENTS

Section 904(a)(1) of the act requires that each tobacco product manufacturer or importer submit "a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand" by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of ingredient listing submission.

Section 904(c)(1) of the act requires that a tobacco product manufacturer provide all information required under section 904(a) "at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment" of the Tobacco Control Act.

Section 904(c)(2) of the act requires that a tobacco product manufacturer advise the FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco additive, except for those additives that have been designated by the FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

Section 904(c)(3) of the act requires that a tobacco product manufacturer advise the FDA in writing within 60 days of eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by the FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

To assist persons making these ingredient submissions, FDA has issued its *Guidance for Industry: Listing of Ingredients in Tobacco Products* (Guidance). This Guidance and the Tobacco Control Act are available through the web links listed on page 8.

DEFINITIONS

FDA intends to use the following definitions in implementing the ingredient listing requirements of section 904 of the act.

1. **Additive:** The term "additive" means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical" (section 900(1) of the act (21 U.S.C. 387(1)).

2. **Importer:** The term "importer" means the importer of record at the time of entry of a tobacco product into the United States.

3. **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.

(Continued on next page)

4. **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 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.

5. **Tobacco Product Manufacturer:** The term "tobacco product manufacturer" means "any person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States" (section 900(20) of the act (21 U.S.C. 387(20)). Thus, the term is not limited to persons who manufacture products containing tobacco, but includes anyone who manufactures any tobacco product as defined above.

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See pages 10-13 for Instructions

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

SECTION I - SUBMISSION TYPE

1. Submission Type *(Check only one)**

New Submission

1a. ☐ Ingredient listing for tobacco product(s) on the market as of June 22, 2009

1b. ☐ Ingredient listing for tobacco product(s) not on the market as of June 22, 2009

Update to Previous Submission *(See instructions on pages 10-13 for required fields.)*

1c. ☐ Add, delete, or change the quantity of additive(s)

1d. ☐ Other update *(e.g., address changes) (Specify below)*

SECTION II - SUBMITTER IDENTIFICATION

Submitter Type *(Check one)**

☐ Manufacturer ☐ Importer

Company Name*

Company Headquarters DUNS Number	Company Headquarters FEI Number

Address*	City*

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

Submitter 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 III - TOBACCO PRODUCT IDENTIFICATION

Submit a separate copy of this page for each tobacco product.

1. FDA-Assigned Tracking Number *(TP######)*

2. Tobacco Product Brand/Sub-brand Name or Other Commercial Name* *(e.g., Acme Lights 100's or Acme Reconstituted Tobacco #202)*.

3. If this is an ingredient listing under 904(c)(1), enter the projected date *(mm/dd/yyyy)* on which the product will be introduced into interstate commerce: _____

4. Product Identification Number *(At least one product identification number must be provided if needed to uniquely identify the product.)*

Type of Product Identification Number	*Product Identification Number*
☐ Item/Catalog Number	
☐ SKU Number	
☐ UPC Number	
☐ Other *(Specify below)*	

5. Use of Product *(Check one)**

☐ Consumer Use *(Go to item 5a)* ☐ Further Manufacturing Use *(Go to item 5b)*

5a. Consumer Use Product Category *(Check one, then skip to Section IV)**

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

5b. Further Manufacturing Use Product Category *(Check one)**

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

SECTION IV - INGREDIENT LISTING

Use a separate copy of Section IV for each ingredient you list or update.

Product Name*	Ingredient Name
FDA-Assigned Tracking Number	**Ingredient Number (IN#)**

1. If this is an update to report a change in an additive, identify type of update and the date that the change was made.

1a. ☐ Quantity of additive was increased* Date of change *(mm/dd/yyyy)*: _____

1b. ☐ Quantity of additive was decreased* Date of change *(mm/dd/yyyy)*: _____

1c. ☐ Additive was eliminated* Date of change *(mm/dd/yyyy)*: _____

1d. ☐ Additive was added* Date of change *(mm/dd/yyyy)*: _____

PART 1: INGREDIENT IDENTIFICATION *(Complete only A, B, or C, as appropriate)*

A. Single Chemical Substance

1. Unique Scientific Name or Code*

2. Type of Code ☐ FDA UNII Code ☐ CAS Number ☐ IUPAC Name ☐ Other *(Specify)*: _____

3. Is this Ingredient a Reaction Product? ☐ Yes *(See immediately below)* ☐ No *(Skip to Part 2)*

If Yes, FDA requests that you list the IN# of all ingredients known or intended to form this product.

IN#	IN#	IN#
IN#	IN#	IN#

B. Leaf Tobacco

1. Type *(e.g., Burley, Bright, Oriental)**	2. Variety*

3. Cure Method *(Select only one)** ☐ Air ☐ Steam ☐ Fire ☐ Sun ☐ Flue ☐ Other *(Specify)*: _____

4. Heat Source *(e.g., propane, wood)**

5. Describe any DNA recombinant technology used to engineer the tobacco *(If none, enter "none")**

C. Complex Purchased Ingredients

Enter the manufacturer's name and the unique identifying item name and/or number used by the manufacturer. If you obtain this ingredient from multiple sources, enter all identifying information for each source below. You may use continuation pages as necessary.

1a. Manufacturer Name*	1b. Unique Identifying Item Name and/or Number*

SECTION IV - INGREDIENT LISTING *(Continued)*	
Product Name*	Ingredient Name
FDA-Assigned Tracking Number	Ingredient Number (IN#)

PART 1 *(Continued)*

C. Complex Purchased Ingredients *(Continued)*

2. Is this ingredient made to your specifications?* ☐ Yes *(See immediately below)* ☐ No *(Skip to Part 2)*

If Yes, enter each specified ingredient by IN#. You may use continuation pages if necessary. We also request that you attach specifications for this ingredient (e.g., release specifications).*

IN#	IN#	IN#
IN#	IN#	IN#

PART 2: INGREDIENT DETAILS

1. Quality *(e.g., % purity, published standard)*

2. Expected Function(s) *(Identify all that apply; use Appendix A for list of functions.)*

3. Part ingredient is added to *(Check all that apply)**

☐ Paper ☐ Other *(Specify)*: _____

☐ Filter ☐ Tobacco *(Specify)*: _____

PART 3: QUANTITY

1. Quantity*	1a. Unit* ☐ g ☐ mg ☐ mcg ☐ ng ☐ pg	1b. Reported per* ☐ Unit of Use ☐ Gram of Product

2. Enter targeted outcome if variable amount has been added to achieve specific product characteristics *(e.g., achieve pH of 7.1).**

3. If you approximated quantity at or near "0," enter limit of detection.*	3a.Unit* ☐ g ☐ mg ☐ mcg ☐ ng ☐ pg

PART 4: ADDITIONAL COMMENTS

Please provide any additional information or comments about this ingredient, including any internal identifying numbers. If you are adding, deleting, or changing the quantity of an ingredient, please explain why the change was made. If changing the quantity of an ingredient, you are also required to include the quantity prior to the change.

SECTION V - 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 904(c) 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

- ☐ Submitter *(Listed in Section II)*
- ☐ 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 Listing of Ingredients in Tobacco Products*:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm

Reference for SRS UNII:
http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm

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

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 3.0 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 Operations
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 - INGREDIENT FUNCTION LIST

1. Addictiveness enhancer (including nicotine addictiveness enhancer such as an agent that affects the dosing, perception or action of nicotine)
2. Adhesive
3. Binder
4. Carrier
5. Casing
6. Chemo-sensory agent that affects perception of smoke including side-stream smoke (including smoke color modifiers, smoke odor modifiers and smoke enhancers)
7. Color
8. Combustion modifier
9. Fiber
10. Filler
11. Filtration
12. Flavor
13. Humectant
14. Plasticizer
15. Preservative
16. Processing aid
17. Reduced ignition propensity
18. Solvent
19. Sizing agent
20. Wrapper
21. Other *(Specify below)*

INSTRUCTIONS

Please note that required fields in this form are designated by an asterisk.

NEW SUBMISSIONS

For additional details and instructions on specific questions, please refer to the FDA Guidance for Industry: Listing of Ingredients in Tobacco Products.

Section I - Submission Type

Item 1a: Check if you are submitting ingredient information, under section 904(a)(1) of the act, for tobacco product(s) manufactured as of June 22, 2009. Move to Section II.

Item 1b: Check if you are submitting ingredient information, under section 904(c)(1) of the act, for tobacco product(s) introduced into interstate commerce after June 22, 2009. Continue to Section II.

Section II - Submission Identification

Identify whether the submitter is the manufacturer or the importer. Under section 904(a)(1), submission of ingredient information for imported products may be submitted by either the manufacturer or the importer. Submission of ingredient information under 904(c)(1) of the act must be submitted by the manufacturer.

If you are reporting as an importer, and you are also a domestic tobacco product manufacturer, then you are also to submit the ingredient information for the products you manufacture. In this situation, you would submit twice -- once as an importer and once as a tobacco product manufacturer.

You must provide the submitting party's name and address. If you are submitting on behalf of the manufacturer or importer as an agent, report information for the manufacturer or importer, not your own information.

Continue to Section III.

Section III - Tobacco Product Identification

If you have previously submitted registration and listing information under section 905 of the act, you should have received an acknowledgement containing FDA-assigned tracking numbers (TP#####) for each of your products. If you choose to enter this tracking number, you may skip items 4 and 5. If you do not have an FDA-assigned tracking number for your product, complete all required identifying information in Section III. Complete this section for each brand and sub-brand for which ingredient information is being submitted. Multiple copies of this page may be submitted. Continue to Section IV.

Section IV - Ingredient Listing

If you are submitting ingredient lists for multiple products in a single submission, enter the product name and/or tracking number at the top of both page 5 and page 6, such that the ingredient information can be linked to a given product. This section should be completed for each ingredient listed. Multiple copies of this section may be submitted.

You should also assign a unique ingredient number (IN#) for each ingredient. This may be done by sequential numbering or by any other system you devise. Keep records of these numbers for reporting updates to your ingredients. Ingredient numbers must be used when linking specified ingredients to complex purchased ingredients.

Part 1: Ingredient Identification

Complete the section of Part 1.A, 1.B, or 1.C, as applicable for the type of ingredient. If you are listing a single chemical substance, for instance, you would complete only Part 1.A before moving on to Part 2.

Part 1.A: Single Chemical Substance

Item 3: If this ingredient is a reaction product, FDA requests that you identify each ingredient known or intended to form this product using their ingredient numbers (IN#). You may use continuation sheets if necessary.

Part 1.B: Leaf Tobacco

Each type of leaf tobacco is to be reported as a separate ingredient. Tobacco that has been processed with any chemical, additive, or substance other than potable water is listed in Part 1.C. Similarly, purchased tobacco blends or reconstituted tobacco are reported in Part 1.C.

Part 1.C: Complex Purchased Ingredients

Item 1: Complex purchased ingredients must be identified by a manufacturer's name and a uniquely identifying item name and/or number. If you obtain this ingredient from multiple sources, you must list the manufacturer's name and uniquely identifying item name and/or number for each source. You may use continuation pages as necessary.

Item 2: For a complex ingredient custom made to your specifications, each specified ingredient must be identified by its ingredient number (IN#). FDA requests that you submit any additional specifications (e.g. release specifications, acceptance criteria, certificate of analysis) by attaching separate pages to this form.

Part 2: Ingredient Details

Complete this section for single chemical substances and complex purchased ingredients.

Part 3: Quantity

Complete this section for all ingredients.

Part 4: Additional Comments

Please use this space to attach any additional information or comments.

Continue to Section V.

Section V - Confirmation Statement

Please sign and date your submission. If you are submitting as an authorized agent, enter all required identifying information in this section. Check your submission to ensure that all continuation pages or attachments are appropriately identified at the top of the page with the product name, FDA-assigned tracking number, ingredient name and IN#, as appropriate.

UPDATES

For additional details and instructions on specific questions, see the corresponding section under "New Submission" or refer to the FDA Guidance for Industry: Listing of Ingredients in Tobacco Products.

Section I - Submission Type

Item 1c: Check if you are updating a previous submission, under sections 904(c)(2) or 904(c)(3) of the act, by reporting the addition of an addition, elimination, or change to the quantity of an additive. Move to Section II.

Item 1d: Check if you are updating a previous submission by reporting any changes to the submission other than the quantity of an additive. Examples of such changes may be changes in the submitter address or point of contact. Move to Section II.

Section II - Submission Identification

Identify whether the submitter is the manufacturer or the importer. Submission of updates under section 904(c) must be submitted by the manufacturer. Submission of updates to any other information may be submitted by either the manufacturer or the importer.

You must provide the submitting party's name and address. If you are submitting on behalf of the manufacturer or importer as an agent, report information for the manufacturer or importer, not your own information.

If you are only reporting an update or correction to contact information contained in Section II, you may skip to Section V. Otherwise, continue to Section III.

Section III - Tobacco Product Identification

If you are updating your product identification number, you must complete items 2 and 4. If this is the only information being updated at this time, you may skip to Section V.

If you are updating ingredient information under sections 904(c)(2) and 904(c)(3) of the act, you must complete all required fields to fully identify the product to which the change is being made. If you enter your FDA-assigned tracking number, you may skip items 4 and 5. This section should be completed for each brand and sub-brand for which ingredient information is being submitted. Multiple copies of this page may be submitted. Continue to Section IV.

Section IV - Ingredient Listing

If you are updating your ingredient list for multiple products in a single submission, enter the product name and/or tracking number at the top of both page 5 and page 6, such that the ingredient information can be linked to a given product. Complete this section for each ingredient listed. Multiple copies of this section may be submitted.

For each update being reported, identify the type of update and the actual or projected date that the update was or will be made.

Part 1: Ingredient Identification

Complete the section of Part 1 (A, B, or C) that applies to the additive being reported. If, in Section IV, you enter both the Ingredient Name and Ingredient Number (IN#) that you used in your previous submission for this ingredient, then you may skip to Part 2.

Part 1.A: Single Chemical Substance

If you are reporting any update to a Single Chemical Substance, you must complete all required fields in this section.

Part 1.B: Leaf Tobacco

If you are reporting any update to leaf tobacco, you must complete all required fields in this section.

Part 1.C: Complex Purchased Ingredients

If you are eliminating or reporting a change (increase or decrease) in the quantity of an additive, you may skip item 2.

For new additives, you must complete all required fields. If you obtain, or plan to obtain, this ingredient from multiple sources, you are to complete all identifying information for each source. If you are reporting a new ingredient custom made to your specifications, you must also list each ingredient that you specified to be used in the manufacturing process.

Part 2: Ingredient Details

If you are eliminating or reporting a change (increase or decrease) in the quantity of an additive, you may skip to Part 3. If you are reporting a new single chemical substance or complex purchased ingredient, complete all required fields.

Part 3: Quantity

If you are eliminating an additive, you may skip to Section V. If you are reporting a new additive or a change in the quantity of an additive, complete all required fields.

Part 4: Additional Comments

Please provide any additional information or comments about this ingredient, including any internal identifying numbers. If you are adding, deleting or changing the quantity of an ingredient, please explain why the change was made. If changing the quantity of an ingredient, you are also required to include the quantity prior to the change.

Section V - Confirmation Statement

Please sign and date your submission. If you are submitting as an authorized agent, enter all required identifying information in this section.