DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

LISTING OF INGREDIENTS IN TOBACCO PRODUCTS

Form Approved: OMB No. 0910-0650
Expiration Date: 6/30/2019
(See page 12 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 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.".

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 as of June 22, 2009 (for cigarettes, cigarette tobacco, roll-your-own (RYO), and smokeless tobacco) or [publication date] (for other tobacco products).

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 12. You may also refer to the Definitions and Instructions sections starting on pages 14 and 15.

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See pages 15-17 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 box. Please ensure that all products under this submission meet the definition of the checked submission type.)**

- ☐ **Type a:** Initial submission per 904(a)(1) for other *tobacco* product(s) on the market as of June 22, 2009 *(for cigarettes, cigarette tobacco, RYO, and smokeless tobacco)* or as of *August 8, 2016 (for other tobacco products)*
- ☐ **Type b:** Initial submission per 904(c)(1) for new product(s)
- ☐ **Type c:** Initial submission per 904(c)(1) for modification to existing product(s)
- ☐ **Type d:** Initial submission per 904(c)(2) for modification to existing product(s)†
- ☐ **Type e:** Initial submission per 904(c)(3) for modification to existing product(s)†
- ☐ **Type f:** Amendment to correct previous product ingredient submission(s)††

  If Type f submission, enter the previous product ingredient submission tracking number (STN): TI _ _ _ _ _ _ _

† If modification to a product involves more than one ingredient and is subject to both 904(c)(2) and 904(c)(3) reporting requirements, treat the modification to the product as falling under 904(c)(2).

†† If you are only reporting an update or correction to contact information, do not use this form. Instead, please submit a letter to FDA indicating the update or correction.

SECTION II - SUBMITTER IDENTIFICATION

Submitter Type *(Check one)** ☐ Manufacturer ☐ Importer *(Complete Section III)*

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

Authorized Representative *(Continued)*

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

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

SECTION III - MANUFACTURER OF IMPORTED PRODUCTS

(Complete if Submitter Type is checked as Importer in Section II)

Note: If you are reporting ingredient information for products from multiple manufacturers, please submit a separate submission for each manufacturer.

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 *(For foreign firm where Authorized Representative does not reside in the U.S.)*

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 company previously identified as manufacturer, and skip to Address.

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

SECTION IV - TOBACCO PRODUCT IDENTIFICATION

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

2. FDA-Assigned Tracking Number

TP _ _ _ _ _ _ _

3. If this product is under review or has been authorized under a marketing pathway, enter the submission tracking number (STN) of the application *(e.g., SE1234567)*

_ _ _ _ _ _ _ _ _

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 (Stock Keeping Unit)	
☐ UPC Number (Universal Product Code)	
☐ EAN (International Article Number)	
☐ GTIN (Global Trade Item Number)	
☐ Other *(Specify below)* _____	

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

☐ Consumer Use ☐ Further Manufacturing Use ☐ Consumer Use and Further Manufacturing Use

6. Is this tobacco product a co-package?*

☐ Yes ☐ No

7. Product Category and Subcategory, or Category and Component*

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

    _____
  - ☐ Cigarette Component
- ☐ **Cigars**
  - ☐ Filtered, Sheet-Wrapped Cigar
  - ☐ Unfiltered, Sheet-Wrapped Cigar
  - ☐ Leaf-Wrapped Cigar
  - ☐ Cigar Component
- ☐ **Electronic Nicotine Delivery Systems (ENDS)**
  - ☐ Closed E-Cigarette
  - ☐ Open E-Cigarette
  - ☐ Open E-Liquid
  - ☐ Closed E-Liquid
  - ☐ ENDS Component
- ☐ **Pipe Tobacco Products**
  - ☐ Pipe
  - ☐ Pipe Tobacco Filler
  - ☐ Pipe Component
- ☐ **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 Component
- ☐ **Smokeless Tobacco Products**
  - ☐ Loose Moist Snuff
  - ☐ Portioned Moist Snuff
  - ☐ Loose Snus
  - ☐ Portioned Snus
  - ☐ Loose Dry Snuff
  - ☐ Dissolvable
  - ☐ Loose Chewing Tobacco
  - ☐ Portioned Chewing Tobacco
  - ☐ Smokeless Tobacco Product Component
- ☐ **Waterpipe Tobacco Products**
  - ☐ Waterpipe
  - ☐ Waterpipe Tobacco Filler
  - ☐ Waterpipe Heat Source
  - ☐ Waterpipe Component
- ☐ **Other Tobacco Products** *(Specify below)*

  _____

  _____

  _____

8. **Tobacco Product Identification Information** – In the table below, you may record the identification information for any tobacco product(s) that you manufacture that are identical to the product listed in item 1 above other than packaging differences that do not affect the characteristics of the product. You do not then need to submit separate ingredients listings (Sections V and VI) for each of the products.

Tobacco Product Brand/Sub-brand Name or Other Commercial Name (e.g., Acme Lights 100's or Acme Reconstituted Tobacco #202*	*Tobacco Product Tracking Number[1] (TP########)*	*Submission tracking number for this product[2] (e.g., SE1234567)*	*Product Identification Number[3]*	*Type of Product Identification Number (see list below)*

If you have additional products to submit, you may attach additional pages.

Type of Product Identification Number	
1. Item/Catalog Number 2. SKU Number (Stock Keeping Unit) 3. UPC Number (Universal Product Code)	4. EAN (International Article Number) 5. GTIN (Global Trade Item Number) 6. Other (Specify)

[1] EDA Assigned Tobacco Product Tracking Number.

[2] If this product is under review or has been authorized under a marketing pathway, enter the submission tracking number of the application.

[3] If no FDA Assigned Tobacco Product Tracking Number is provided, at least one product identification number must be provided if needed to uniquely identify the product.

SECTION V – COMPONENT IDENTIFICATION

Note: If your tobacco product has multiple components, please submit a separate copy of Section V for each component you list or update.

Product Name *(As recorded in Section IV)**	Product Category *(As recorded in Section IV)**

Component Type *(Select the component type based on the product category.)**

Cigarette Component Types

- ☐ Tobacco Filler
- ☐ Tobacco Filler Additive
- ☐ Adhesive
- ☐ Filter
- ☐ Ink (Rod Print)
- ☐ Pack Inner Foil
- ☐ Cigarette Paper
- ☐ Tipping Paper
- ☐ Plug Wrap
- ☐ Other *(Specify below)*

_____

Cigar Component Types

- ☐ Tobacco Filler
- ☐ Tobacco Filler Additive
- ☐ Adhesive
- ☐ Filter
- ☐ Tip
- ☐ Tipping Paper
- ☐ Plug Wrap
- ☐ Wrapper/Binder
- ☐ Other *(Specify below)*

_____

ENDS Component Types

- ☐ Atomizer
- ☐ Coil/Coil Heads
- ☐ E-Liquid
- ☐ Mouthpiece
- ☐ Tank/Cartridge
- ☐ Wick
- ☐ Other *(Specify below)*

_____

Pipe Component Types

- ☐ Tobacco Filler
- ☐ Tobacco Filler Additive
- ☐ Bowl
- ☐ Mouthpiece
- ☐ Shank (without bowl)
- ☐ Other *(Specify below)*

_____

Roll-Your-Own Component Types

- ☐ Tobacco Filler
- ☐ Tobacco Filler Additive
- ☐ Adhesive
- ☐ Filter
- ☐ Ink (Rod Print)
- ☐ Cigarette Paper
- ☐ Tipping Paper
- ☐ Plug Wrap
- ☐ Other *(Specify below)*

_____

Smokeless Tobacco Product Component Types

- ☐ Tobacco Filler
- ☐ Tobacco Filler Additive
- ☐ Pouch
- ☐ Other *(Specify below)*

_____

Waterpipe Component Types

- ☐ Tobacco Filler
- ☐ Tobacco Filler Additive
- ☐ Heat Source
- ☐ Base
- ☐ Bowl
- ☐ Diffuser
- ☐ Foil/Screen
- ☐ Hose
- ☐ Mouthpiece
- ☐ Seal
- ☐ Stem
- ☐ Valve
- ☐ Other *(Specify below)*

_____

Other Tobacco Products *(Specify component type below)*

_____

_____

_____

Component Name *(e.g., Name/type of adhesive, such as Cigarette Rod Adhesive, Tipping Adhesive, Filter Seam Adhesive, Anchor Line Adhesive; or Name/type of tobacco filler additive, such as Casing Tobacco Filler Additive, Top Flavoring Tobacco Filler Additives). (Component Name with same composition if count is other than one (1) (e.g., water pipe hoses, count 3; coils, count 5)*.

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

*Manufacturer Name**	*Manufacturer's Uniquely Identifying Component Name and/or Number**

SECTION VI – INGREDIENT LISTING

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

Product Name *(As recorded in Section IV)**	Component Type and Name *(As recorded in Section V; or record "NA" if not applicable)**

Ingredient Name*	Ingredient Number (IN#)*

1. If submission type d or type e is checked in Section I, indicate the type of additive change *(Check only one)**

- ☐ Quantity of additive was increased* Date of change *(mm/dd/yyyy)*: _____
- ☐ Quantity of additive was decreased* Date of change *(mm/dd/yyyy)*: _____
- ☐ Additive was eliminated* Date of change *(mm/dd/yyyy)*: _____
- ☐ 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

1a. Unique Scientific Name

1b. Type of Name *(Select one)*

☐ IUPAC Name ☐ Other *(Specify)*: _____

2a. Registry Code

2a. Type of Code

☐ FDA UNII Code ☐ CAS Number ☐ 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 *(e.g., flavor extracts, tobacco leaf blends, reconstituted tobacco, spices, fruit juice, adhesives, charcoal)*

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*

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 *(Applicable to "Single Chemical Substance" and "Complex Ingredient" only. Skip Part 2 for "Leaf Tobacco". You may also skip Part 2 if you are eliminating the ingredient or reporting an increase or decrease in the quantity of the ingredient as you have indicated in Question 1; Under Section VI.)*

1. Quality Unit of Measure and Value *(Check only one and enter value)*

- ☐ Ash Content (%): _____
- ☐ Assayed Contents (%): _____
- ☐ Solids Dry Basis (%): _____
- ☐ Solids Wet Basis (%): _____
- ☐ Moisture (%): _____
- ☐ CORESTA Unit (cm3 min-1 cm-2 at 1 kPa): _____
- ☐ Quality Conforms to a Published Standard – Citation for Standard *(e.g., '21 CFR 175.105', or 'FCC 9 Acesulfame Potassium')*: _____
- ☐ Degrees Brix (^{0} Bx): _____
- ☐ Density (g/cm^3): _____
- ☐ Dextrose Equivalent: _____
- ☐ Proof: _____
- ☐ Specific Gravity (unitless): _____
- ☐ Specific Rotation (degrees): _____
- ☐ Other *(Specify units)*: _____ , Value: _____

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

PART 3: QUANTITY *(You may skip Part 3 if you are eliminating the ingredient, and Question 1 is checked '1c. Additive was eliminated'.)*

1. Unit of Measure*

1a. Unit *(Check one)**	1b. Reported per *(Check one)**
☐ g ☐ mg ☐ mcg ☐ ng ☐ pg	☐ Unit of Use ☐ Gram of Product

2. Quantity *(Check only one and complete the associated field(s).)**

Special Note: For each numeric field, enter a single value. Do not enter a value range (ex: 5.0-10.0, <1).

☐ ***Amount Calculated***

Singular Quantity: _____

☐ ***Amount Tested***

Mean Quantity: _____

Variability *(Check only one then enter values)*:

- ☐ Standard Error: _____
- ☐ 95% Confidence Interval: upper limit _____, lower limit _____
- ☐ Other *(Specify type)*: _____, *(Value)*: _____

☐ ***Amount to Achieve An Outcome***

Target Outcome Type *(Check only one)*:

- ☐ Color
- ☐ pH
- ☐ Total Sugars
- ☐ Moisture
- ☐ Other *(Specify)*: _____

Target Outcome Units and Value(s) *(Check only one then enter values)*:

- ☐ CIE L*a*b*: L*: _____ , a*: _____, b*: _____
- ☐ pH Units: _____
- ☐ Grams of Total Sugars per Unit of Use: _____
- ☐ Grams of Total Sugars per Gram of Product: _____
- ☐ Other *(Specify Unit)*: _____, *(Value)*: _____

Typical Quantity: _____, or Minimum Quantity: _____, and Maximum Quantity: _____

☐ ***Residual Amount***

Residual Quantity: _____, Limit of Detection: _____

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 VII – 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 Authorized Representative or U.S. Agent	Date

☐ Check here if same as the submitter point of contact information in Section II. If so, you may 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 company's, and skip address items.	City*

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

REFERENCES

Reference for the Tobacco Control Act:
http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm

Reference for *Guidance on Listing of Ingredients in Tobacco Products*:
http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm

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

For regulatory questions regarding sections 904 and 905 of the 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 ADDRESS BELOW.

The burden time for this collection of information is estimated to average 3 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 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. Aerosol forming agent
4. Anti-foaming agent
5. Anti-plasticizer
6. Anti-sticking agent
7. Antioxidant
8. Binder
9. Biocide
10. Carrier
11. Casing
12. Chemo-sensory agent that affects perception of mainstream or sidestream smoke including smoke color modifiers, smoke odor modifiers and smoke enhancers)
13. Coating agent
14. Color
15. Combustion modifier
16. Dispersant
17. Drying agent
18. Emulsifier
19. Fermentation agent
20. Fiber
21. Filler
22. Film-forming agent
23. Filtration
24. Flavor
25. Fuel for heat source
26. Heat conductor
27. Heat insulator
28. Humectant
29. Ink
30. Lip release agent
31. Menthol delivery
32. Moisture barrier
33. Moisturizer
34. Nicotine source
35. Oxygen barrier
36. pH adjuster
37. pH buffer
38. Plasticizer
39. Porosity control agent
40. Preservative
41. Processing aid
42. Reduced ignition propensity
43. Sizing agent
44. Solvent
45. Surfactant
46. Sweetener
47. Texture control agent
48. Whitener
49. Wrapper
50. Other *(Specify below)*:

_____

_____

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. **Co-package:** A co-package is a tobacco product that is offered for sale containing multiple distinct tobacco products (e.g., a can of RYO tobacco that includes a booklet of rolling paper), as opposed to containing a quantity of the same tobacco product (e.g., a pack of 20 cigarettes).

3. **Component or Part:** Component or part means any software or assembly of materials intended or reasonably expected: 1) to alter or affect the tobacco product’s performance, composition, constituents or characteristics; or 2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.

4. **Importer:** The term “importer” means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States.

5. **Manufacturer:** The term manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished tobacco product.

6. **Pouch:** The term “pouch” means a permeable material, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.

7. **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.

INSTRUCTIONS

NOTE: Required fields in this form are designated by asterisks (*).

NOTE: Sections I, II, III, IV and VII only need to be completed once for each unique tobacco product or tobacco product co-package.

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

Section I – Submission Type

Check one Submission Type as appropriate. Please refer to definitions on page 1 and the special notes on the bottom of Section I.

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.

Section III – Manufacturer of Imported Products

Complete all contact fields as indicated. If you are reporting ingredient information for products from multiple manufacturers, please submit a separate submission for each manufacturer.

Section IV – 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 item 4. If you do not have an FDA-assigned tracking number for your product, complete all required identifying information in Section IV. Complete this section for each brand and sub-brand for which ingredient information is being submitted.

Report in item 5 if the product is to be sold to consumers for their use, for further manufacture, or both sale for consumer use and also further manufacture.

Report in item 7 the Category and Subcategory or Category and Component for all tobacco products.

> For example: if you were reporting on a finished cigarette you might check category: "Cigarettes", subcategory: "Combusted, Filtered" and then move to Section V to provide each component and its ingredients. Alternatively, if you were reporting on a cigarette filter sold for further manufacture you might check category cigarette and component and then move to Section to fill out component type.

For reporting of a co-packaged product, consisting of multiple product categories and/or subcategories, check the Yes box at item 6 and all relevant boxes in item 7.

> For example: if you were reporting on a Roll-Your-Own Tobacco Filler with Rolling Papers included, you would check category: "Roll-Your-Own Tobacco Products", subcategory: "Roll-Your-Own Tobacco Filler",

and subcategory: “Rolling Paper”. You would then move to Section V to provide each component and its ingredients.

Section V – Component Identification

Complete all fields as indicated. If this tobacco product has multiple components, list each component and its ingredients separately. Complete a separate copy of Section V for each component for which ingredient information is being submitted.

For Component Type, enter only a single component type and the specific component name here each time. If the reported product is a co-packaged product consisting of components of more than one product category (e.g., Cigarette and RYO), ensure to identify the product categories and the component names (e.g., Cigarette Filter; RYO Filter).

For example if you are reporting on the adhesives for cigarettes including the tipping paper and the rod, you would report the component type as adhesive and the specific component name as tipping paper adhesive and then you would list the ingredients within that tipping paper adhesive; you would then fill out Section V for cigarette rod adhesive and provide the ingredients for the cigarette rod.

Section VI – Ingredient Listing

If you are submitting ingredient lists for multiple products in a single submission, enter the product name and/or tracking number on Sections IV, V and VI, 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 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, tobacco blends or reconstituted tobacco is reported in Part 1.C.

Part 1.C: Complex Ingredients

Item 1: Complex 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 ingredients. If you are eliminating or reporting a change (increase or decrease) in the quantity of an additive, you may skip Part 3. If you are reporting a new single chemical substance or complex ingredient, complete all required fields.

Part 3: Quantity

Complete this section for all ingredients. If you are eliminating an additive, you may skip to Section VII. 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 attach or use this space to provide any additional information or comments about this ingredient, including any internal identifying numbers. If you are adding, eliminating 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.

NOTE: All ingredient information included in Section VI corresponding to a component listed in Section V, should be attached (in a paper form) immediately after the component information in Section V. For example, following the information for the e-liquid component of an ENDS tobacco product, should be separate ingredient information sheets corresponding to each of the ingredients in the e-liquid (e.g., nicotine, propylene glycol, glycerin, flavorant).

Section VII - Confirmation Statement

Please sign and date your submission. 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.