



Template Name: Tobacco Product Ingredient Listing  
File Name: TOBACCO\_INTRO\_904.xml

Version: 1.0  
Last Modified: 11/20/2009 05:06:53 PM

Outline

- Listing of Ingredients
- Overview
- Instructions
- Identification
- Submission Content
- Instructions
  - Manufacturer Identification
  - Importer Identification
- Product Identification
  - Ingredient Identification

Screen: Overview

## Listing of Ingredients in Tobacco Products

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. Among its many provisions, the Tobacco Control Act added section 904 to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d), establishing requirements for tobacco product ingredient submissions. To view the Tobacco Control Act, see [Public Law citation \(Pub. Law 111-31\)](#).

Complete the following question and answer form to list your ingredients and submit the required data to FDA's Center for Tobacco Products via the FDA Electronic Submissions Gateway (ESG). To register with the FDA ESG, go to [www.fda.gov/esg/](http://www.fda.gov/esg/).

For your reference, see the [Draft Guidance: Listing of Ingredients in Tobacco Products](#) (Will be updated to Final).

Please note, there are several icons within the application to help guide you. Most importantly, the light bulbs indicate additional instructions, definitions, and other helpful hints.

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. The OMB control number for this information collection [insert OMB control number] (expires [insert expiration date]).

**Blue dots indicate required fields.**



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Screen: Instructions

## Introduction > Submitter Identification > Ingredient Listing > Confirmation

You are in the **Introduction** section. In this section you will be asked to identify your role and type of submission (new or update to previous submission).

Based on your answers to this section, the application will tailor subsequent questions to ensure that you only answer those questions relevant to you.

To help you create your eSubmitter Submissions for the Center for Tobacco Products, see the [Submission Checklist and Working Instructions](#).



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Screen: Identification

## Statutory Requirements

The requirements under section 904(a)(1) of the act apply to each tobacco product manufacturer or importer. Domestic manufacturers are to submit the required ingredient information for products they manufacture and, for tobacco products that are imported, the required ingredient information is to be submitted by either the foreign manufacturer or the importer of the product. This includes any tobacco product, whether for consumers or for further manufacturing.

*Please note: For tobacco products that are imported, the required ingredient information is to be submitted by either the foreign manufacturer or the importer of the product. 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*

For information regarding the section 904 requirements, please refer to the [Draft Guidance: Listing of Ingredients in Tobacco Products](#) (Will be updated to Final version).

Please identify your role:



- Importer
- Tobacco Product Manufacturer



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Screen: Submission Content

Select the appropriate submission status:

New Submission

Update to a Previous Submission



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Screen: Instructions

Introduction > **Submitter Identification** > Ingredient Listing > Confirmation

You are in the **Submitter Identification** section. This section requests contact and address information for the responsible individual submitting the Ingredient Listing submission.




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Screen: Manufacturer Identification

Please provide your contact information below:  

**Contact**

Title (Mr., Ms., Dr.):	<input type="text"/>
First/Given Name:	<input type="text"/>
Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>
Position Title:	<input type="text"/>
Email Address:	<input type="text"/>

**Address**

Company Name:	<input type="text"/>
Country:	<input checked="" type="radio"/> <b>United States of America</b> <input type="radio"/> <b>Other (select below)</b> <input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State, Province, or Territory:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>

**Phone Numbers**

Telephone number:	<input type="text"/> ( ) - - Ext. <input type="text"/>
Fax number:	<input type="text"/> ( ) - - <input type="text"/>

**Reference Numbers (for the Company Name specified above)**

FDA Establishment Identifier (FEI):	<input type="text"/>
D&B D-U-N-S Number:	<input type="text"/>



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Screen: Importer Identification

Please provide your contact information below:



Contact

Title (Mr., Ms., Dr.):	<input type="text"/>
First/Given Name:	<input type="text"/>
Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>
Position Title:	<input type="text"/>
Email Address:	<input type="text"/>

Address

Company Name:	<input type="text"/>
Country:	<input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below) <input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State, Province, or Territory:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>

Phone Numbers

Telephone number:	<input type="text"/>
Fax number:	<input type="text"/>

Reference Numbers (for the Company Name specified above)

D&B D-U-N-S Number:	<input type="text"/>
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Screen: Instructions

## Introduction > Submitter Identification > **Ingredient Listing** > Confirmation

You are in the **Ingredient Listing** section. In this section you will enter each product and the ingredients in each product.

*Please note: If you submitted an Establishment Registration and Product Listing submission using eSubmitter and via the FDA's ESG, you can import certain product identification information received in the Excel spreadsheet as part of your automated acknowledgement message.*





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Screen: Product Identification

Product Listing

Buttons: Add, Delete, Delete All, List, Detail, Info, Up Arrow, Down Arrow

**How to Enter Your Product(s):**

You may enter data directly into this screen using the data entry method. As an alternative to data entry, you may enter this information into a pre-formatted spreadsheet that CTP has specifically designed to be imported here.

**Data Entry Method:**

1. To begin, click on the **"Add"** button to enter information about a product.
2. Then, advance to the next screen where all ingredients should be entered for the selected product. You should enter all ingredients for a given product.
3. Once you have entered all of the ingredient information for a product, you should return to this screen to list another product. If you do not need to list another product, you can continue to the next section after Ingredients.

**Import Method:**

1. Click on the link ([Import Spreadsheet Template for Product Identification](#)) to launch the pre-formatted Excel spreadsheet.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information. You will need to navigate to the location of the file during the import process.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner of this screen next to the yellow light bulb and follow the import wizard.
5. After all data is imported, you can click on the **"List"** button to view and verify the imported product(s) information.

To see these instructions again, you may click on the **"Info"** button.



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Screen: Product Identification

Product Listing

**Add** **Delete** **Delete All** **List** **Detail** **Info**

Item: 1

### PRODUCT IDENTIFICATION

Enter the product name (i.e., brand/sub-brand or other commercial name):

A product identification number must be provided if needed to uniquely identify the product:

Select the type of product identification number:

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

Select use of this product:

Select the product category:

If Other, please describe further:



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Screen: Ingredient Identification

Ingredient Listing By Product

Product No Data Provided

+ Add - Delete Delete All List Detail Info ↑ ↓

**How to Enter the Ingredient Information for each Product:**

List all ingredients for the product that was entered and selected in the previous screen (displayed in the "Product" header above). To facilitate data entry, please enter reaction products after entering all other ingredients.

You may enter data directly into this screen using the data entry method. As an alternative to data entry, you may enter this information into a pre-formatted spreadsheet that CTP has specifically designed to be imported here.

**Data Entry Method:**

1. To begin, click on the **"Add"** button to enter information about a particular ingredient.
2. Once you have entered the information about a particular Ingredient, click on the **"Add"** button to enter information about another ingredient.
3. Repeat steps 1 and 2 until all ingredients have been entered for the product identified above.
4. After you have entered all ingredients for the selected product, return to the Product Identification screen to enter another product. Select the next product in the List and advance to this screen to add the Ingredient information.

**Import Method:**

1. Click on the link ([Import Spreadsheet Template for Ingredient Identification](#)) to launch the pre-formatted Excel spreadsheet.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information. You will need to navigate to the location of the file during the import process.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner of this screen and follow the import wizard.
5. After all data is imported, you can click **"List"** to view and verify the imported product(s) information.

To see these instructions again, you may click on the **"Info"** button above.



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Screen: Ingredient Identification

### Ingredient Listing By Product

Product: No Data Provided

Buttons: Add, Delete, Delete All, List, Detail, Info, Up, Down

Item: 1

**PART 1: INGREDIENT IDENTIFICATION**

Enter the ingredient name (required if linking ingredients to reaction products or complex purchased ingredients):

Identify the type of ingredient:

**Single Chemical Substance**

Enter the unique scientific name or code:

Select the type of code:

if "Other" type, specify further:

Is this ingredient a reaction product?

If yes, list all ingredients known or intended to react to form this reaction product by clicking on the plus (+) sign.

0 of 50 items in the list

**Leaf Tobacco**

Enter the tobacco type (e.g., Burley, Bright, Oriental):

Enter variety:

Select cure method:

if "Other..." method, specify further:

Enter heat source (e.g., propane, wood):

Describe any DNA recombinant technology used to engineer the tobacco (if none, enter "None"):

**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.

0 of 50 items in the list

Is this ingredient custom made to your specifications?

If yes, select each specified ingredient by clicking on the plus (+) sign.

0 of 50 items in the list

If yes, attach any specifications for this ingredient (e.g. certificate of analysis, release specifications, acceptance criteria).

0 items in the list

Title	Name	Date	Size

Comments Regarding Attachments



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Screen: Ingredient Identification

Ingredient Listing By Product

Product No Data Provided  
Add Delete Delete All List Detail Info

Item: 1

**PART 2: INGREDIENT DETAILS**

Enter the Quality (e.g., % purity, a published standard) of the ingredient:

Select ingredient function(s):  
0 of 6 items in the list

If Other, please specify:

Identify part(s) ingredient is added to:  
0 of 6 items in the list (0 required)

If Tobacco, please specify to which kind of tobacco the ingredient was added (e.g., reconstituted tobacco, expanded tobacco, leaf tobacco):

If Other, please specify:

**PART 3: QUANTITY**

Enter quantity of ingredient (see guidance document, section III.C.5):

Select the unit of measure:

Select the quantity reported per:

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

Enter limit of detection (required if quantity is "0" or negligible; see guidance document):

Select the unit of measure for the limit of detection (required if limit of detection specified; see guidance document):

**PART 4: COMMENTS**

Please provide any additional information or comments about this ingredient, including any internal identifying numbers. If you 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.



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- Listing of Ingredients
- Confirmation
- Instructions
- Confirmation Statement
- Package Files for Submission

Screen: Instructions

## Introduction > Registration > Product Listing > **Confirmation**

You are now in the **Confirmation** section. This section contains a confirmation statement, and requests additional contact and address information, as needed. Your last step in this section is to package your submission for transmission to the Center for Tobacco Products.

The packaging process will validate that you have completed data entry.

**CeSub eDesigner**

File Edit View Designer Output Tools Help


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**Outline**

- Listing of Ingredients
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Instructions  
 Confirmation Statement  
 Package Files for Submission

**Screen: Confirmation Statement**

 Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

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 of the Act.  **Agree**

Identify the person submitting this form:

▶ If authorized Agent, enter your name and address.  

Title (Mr., Ms., Dr.):	<input type="text"/>
First/Given Name:	<input type="text"/>
Middle Name:	<input type="text"/>
Last Name:	<input type="text"/>
Position Title:	<input type="text"/>
Email Address:	<input type="text"/>
Company Name:	<input type="text"/>
Country:	<input checked="" type="radio"/> United States of America <input type="radio"/> Other (select below) <input type="text"/>
Address - Line 1:	<input type="text"/>
Address - Line 2:	<input type="text"/>
City:	<input type="text"/>
State, Province, or Territory:	<input type="text"/>
Post Office or Zip Code:	<input type="text"/>
Telephone number:	( ) - - Ext
Fax number:	( ) - -

OMB No. XXXXX, Expiration Date: XXXXXXXX



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Screen: Package Files for Submission

**STOP** You have reached the end of this submission. You may now package the submission and transmit it to CTP via the ESG or on CD-ROM in order to fulfill your requirements.

At this time, you may save and close this submission to return to it at a later time. To do so, simply click Save and then Close from the File Menu or top Tool Bar. To re-open this submission after closing, select Open Existing Submission from the Intro Screen or Open from the File Menu.

If you would like to package this submission at this time in preparation for transmitting to FDA, please begin the packaging process by selecting Output > Package Files for Submission or by clicking the Package icon from the top toolbar. If any required data is missing, the packaging process will not begin and a Missing Data Report will be displayed. Please ensure that all required questions are completed and all applicable documents have been attached within the submission. Specific directions for packaging your submission can be found in the eSubmitter User Manual and/or Quick Guide.

If you would like to prepare another submission to fulfill other FDA requirements, please select "New" from the File Menu to begin compiling a new submission and be sure to select the appropriate submission type.



