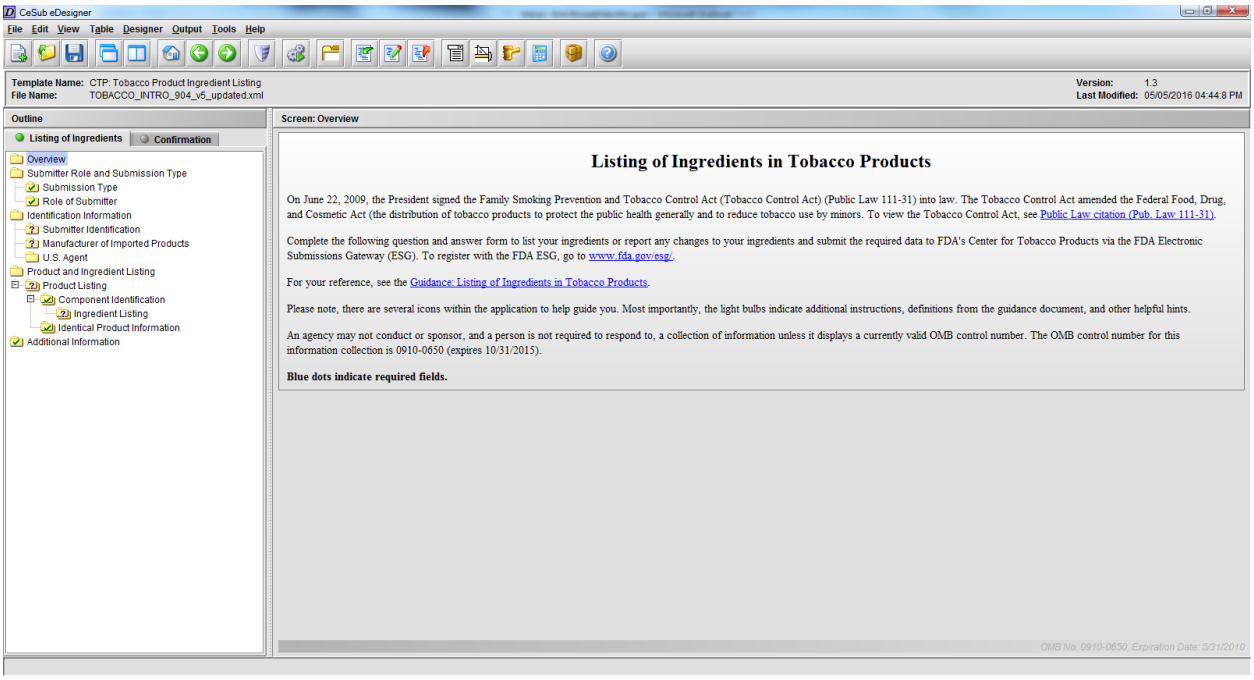
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Template Name: CTP: Tobacco Product Ingredient Listing
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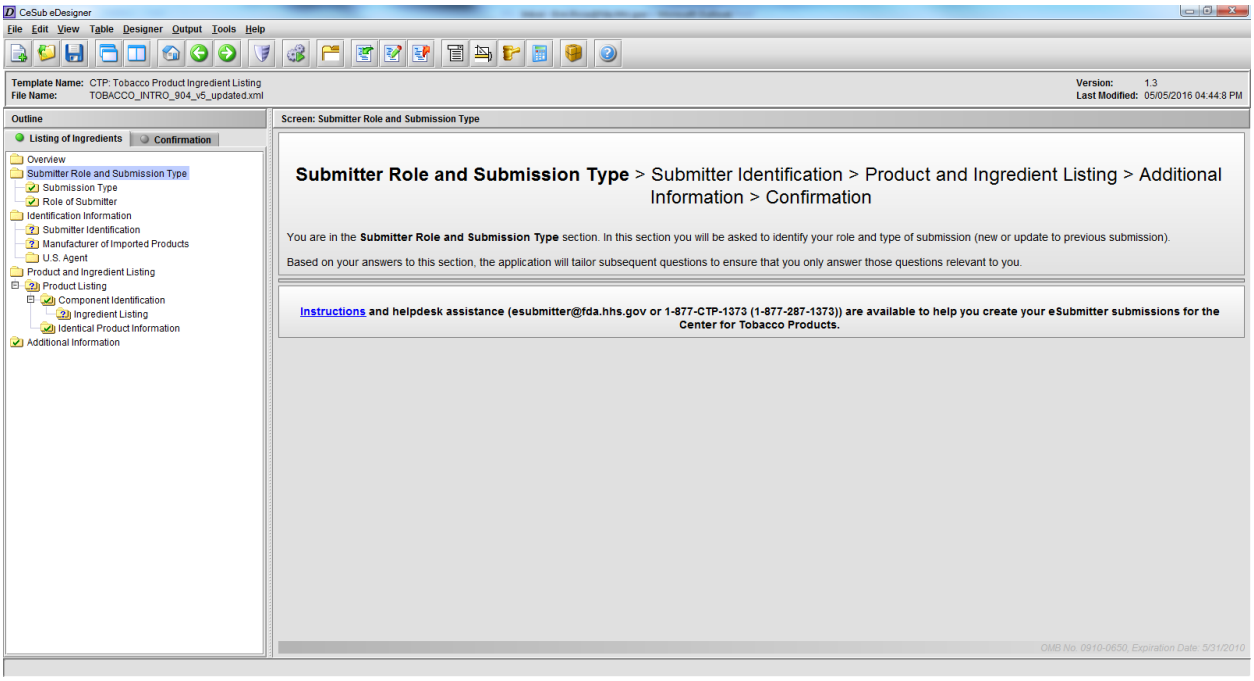
Product Listing
Component Identification
Ingredient Listing
Identical Product Information
Additional Information
Screen: Overview
Listing of Ingredients in Tobacco Products
On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. 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. 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 or report any changes to 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/.
For your reference, see the Guidance: Listing of Ingredients in Tobacco Products.
Please note, there are several icons within the application to help guide you. Most importantly, the light bulbs indicate additional instructions, definitions from the guidance document, 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 is 0910-0650 (expires 10/31/2015).
Blue dots indicate required fields.
OMB No. 0910-0650, Expiration Date: 5/31/2010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File Edit View Table Designer Output Tools Help
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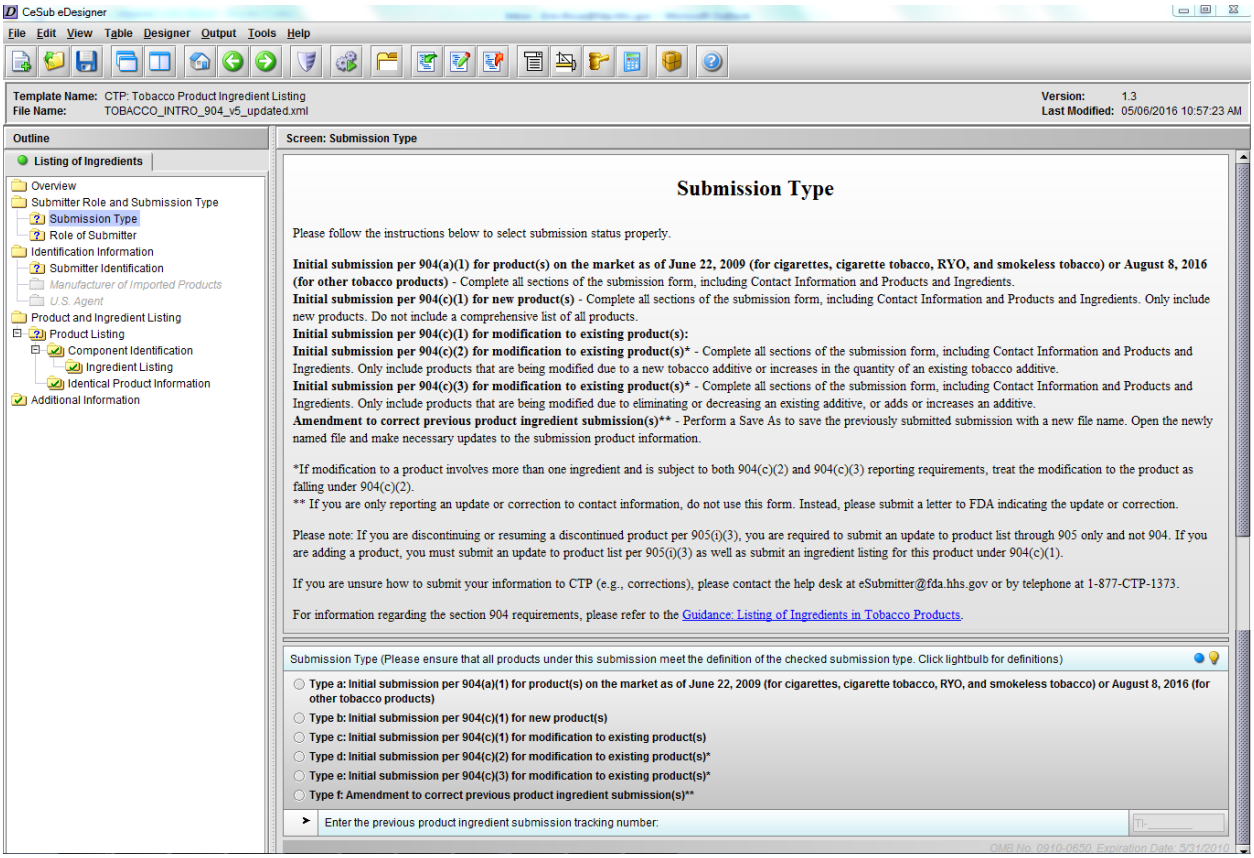
Ingredient Listing
Identical Product Information
Additional Information
Screen: Submitter Role and Submission Type
Submitter Role and Submission Type > Submitter Identification > Product and Ingredient Listing > Additional Information > Confirmation
You are in the Submitter Role and Submission Type section. 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.
Instructions and helpdesk assistance (esubmitter@fda.hhs.gov or 1-877-CTP-1373 (1-877-287-1373)) are available to help you create your eSubmitter submissions for the Center for Tobacco Products.
OMB No. 0910-0650, Expiration Date: 5/31/2010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File Edit View Table Designer Output Tools Help
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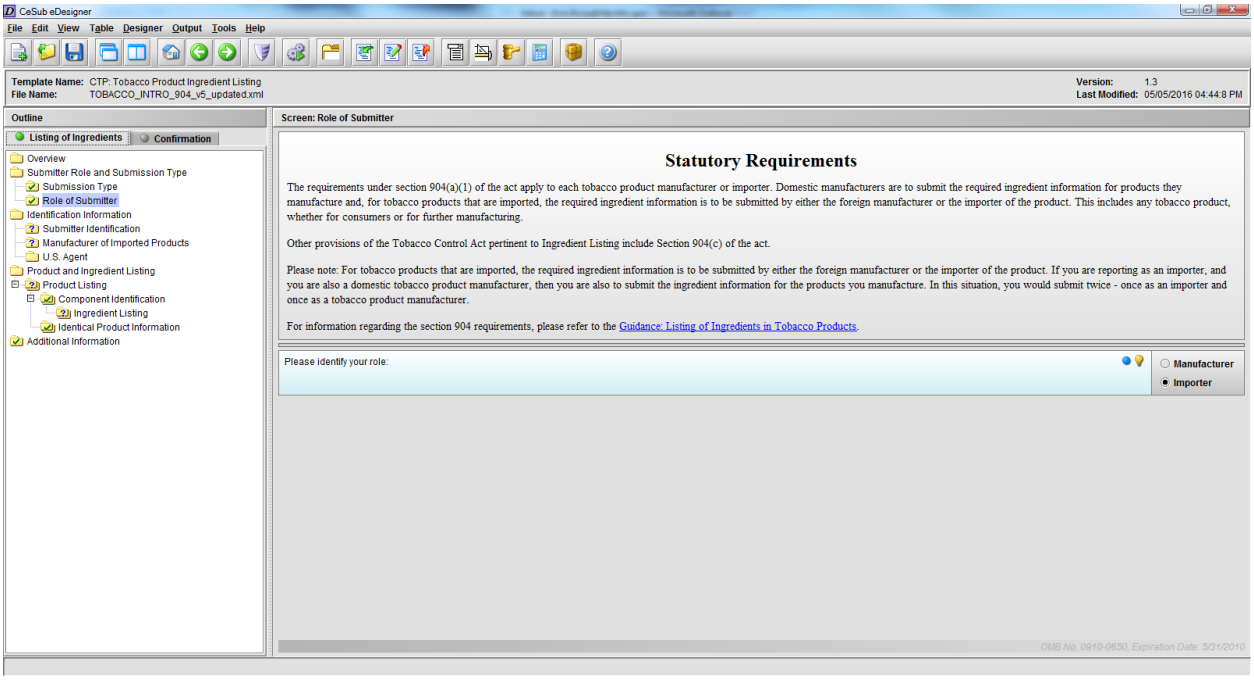
Screen: Submission Type
Submission Type
Please follow the instructions below to select submission status properly.
Initial submission per 904(a)(1) for product(s) on the market as of June 22, 2009 (for cigarettes, cigarette tobacco, RYO, and smokeless tobacco) or August 8, 2016 (for other tobacco products) - Complete all sections of the submission form, including Contact Information and Products and Ingredients.
Initial submission per 904(c)(1) for new product(s) - Complete all sections of the submission form, including Contact Information and Products and Ingredients. Only include new products. Do not include a comprehensive list of all products.
Initial submission per 904(c)(1) for modification to existing product(s):
Initial submission per 904(c)(2) for modification to existing product(s)* - Complete all sections of the submission form, including Contact Information and Products and Ingredients. Only include products that are being modified due to a new tobacco additive or increases in the quantity of an existing tobacco additive.
Initial submission per 904(c)(3) for modification to existing product(s)* - Complete all sections of the submission form, including Contact Information and Products and Ingredients. Only include products that are being modified due to eliminating or decreasing an existing additive, or adds or increases an additive.
Amendment to correct previous product ingredient submission(s)** - Perform a Save As to save the previously submitted submission with a new file name. Open the newly named file and make necessary updates to the submission product information.
*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.
Please note: If you are discontinuing or resuming a discontinued product per 905(i)(3), you are required to submit an update to product list through 905 only and not 904. If you are adding a product, you must submit an update to product list per 905(i)(3) as well as submit an ingredient listing for this product under 904(c)(1).
If you are unsure how to submit your information to CTP (e.g., corrections), please contact the help desk at eSubmitter@fda.hhs.gov or by telephone at 1-877-CTP-1373.
For information regarding the section 904 requirements, please refer to the Guidance: Listing of Ingredients in Tobacco Products.
Submission Type (Please ensure that all products under this submission meet the definition of the checked submission type. Click lightbulb for definitions)
Type a: Initial submission per 904(a)(1) for product(s) on the market as of June 22, 2009 (for cigarettes, cigarette tobacco, RYO, and smokeless tobacco) or 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)**
Enter the previous product ingredient submission tracking number:
OMB No. 0910-0650, Expiration Date: 5/31/2010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File Edit View Table Designer Output Tools Help
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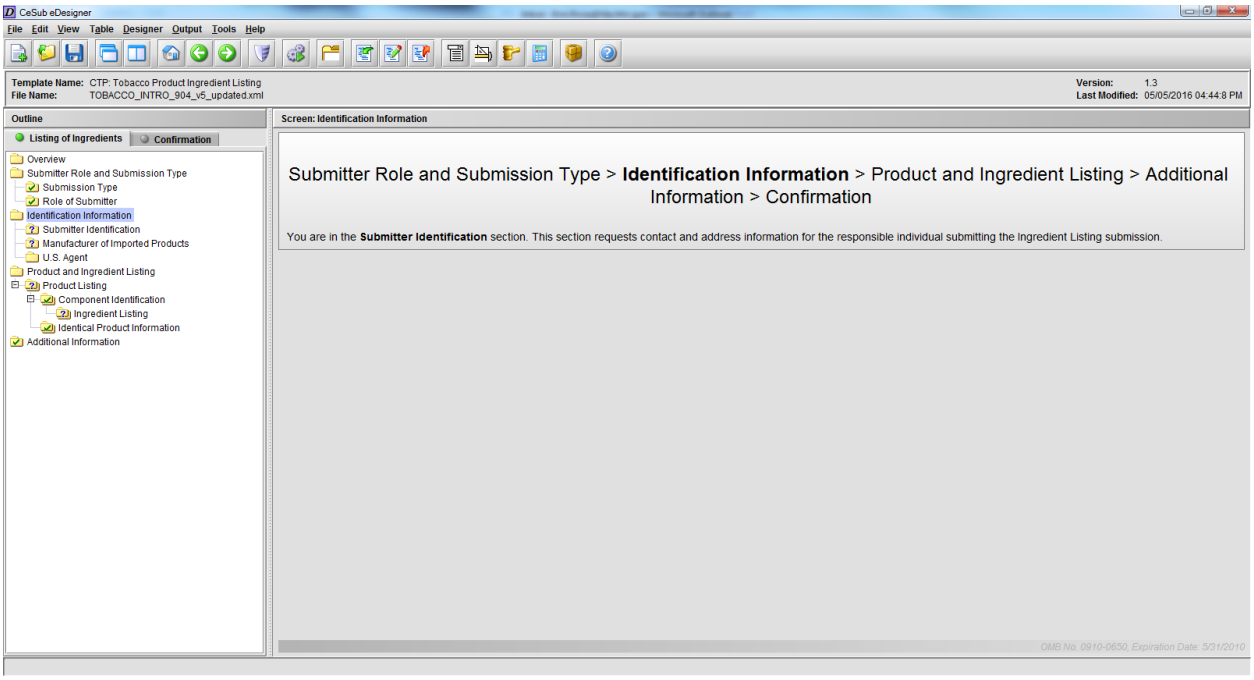
Screen: Role of Submitter
Statutory Requirements
The requirements under section 904(a)(1) of the act apply to each tobacco product manufacturer or importer. Domestic manufacturers are to submit the required ingredient information for products they manufacture and, for tobacco products that are imported, 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.
Other provisions of the Tobacco Control Act pertinent to Ingredient Listing include Section 904(c) of the act.
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 Guidance: Listing of Ingredients in Tobacco Products.
Please identify your role:
Manufacturer
Importer
OMB No. 0910-0650, Expiration Date: 5/31/2010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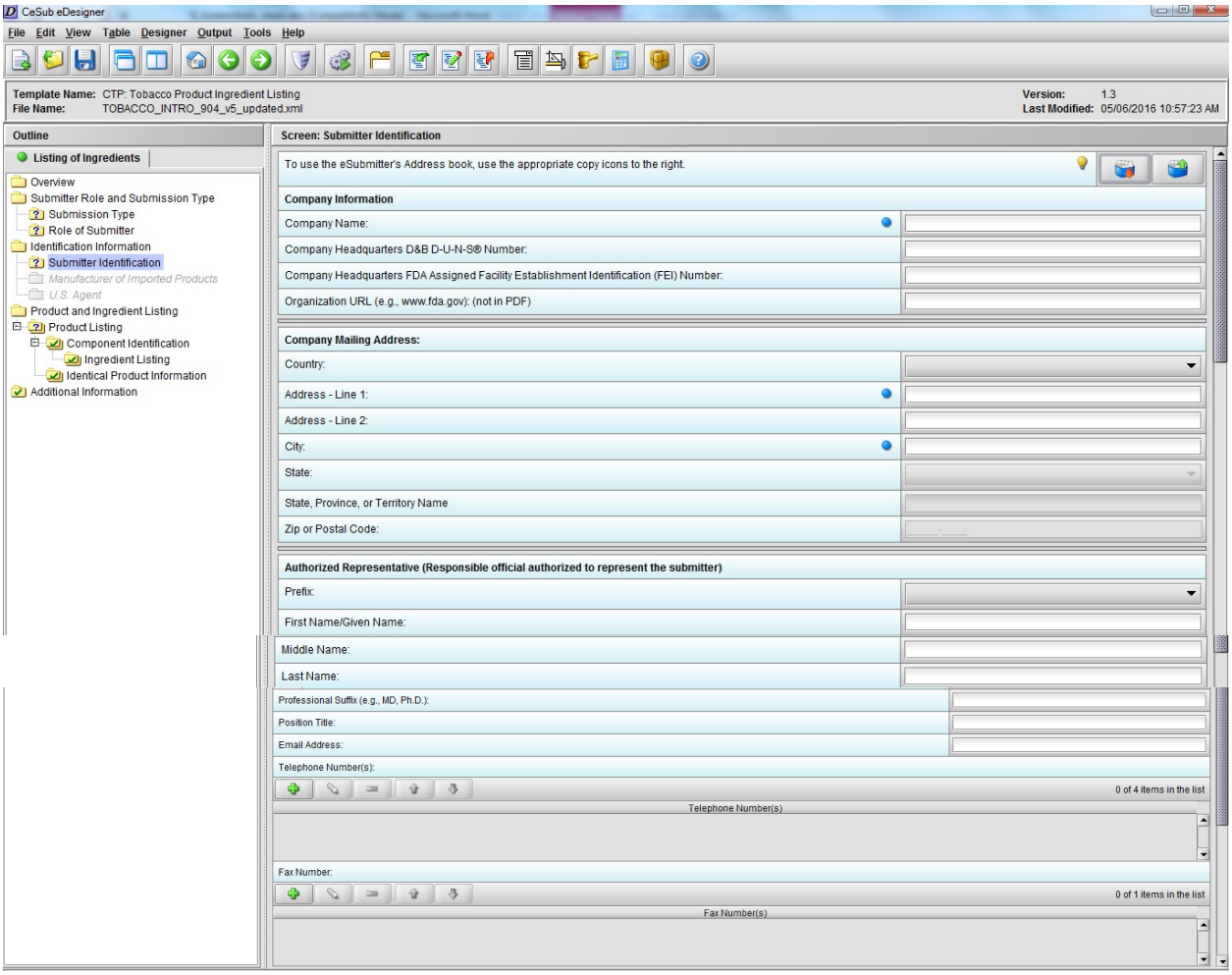
Screen: Identification Information
Submitter Role and Submission Type > Identification Information > Product and Ingredient Listing > Additional Information > Confirmation
You are in the Submitter Identification section. This section requests contact and address information for the responsible individual submitting the Ingredient Listing submission.
OMB No. 0910-0650, Expiration Date: 5/31/2010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Ingredient Listing
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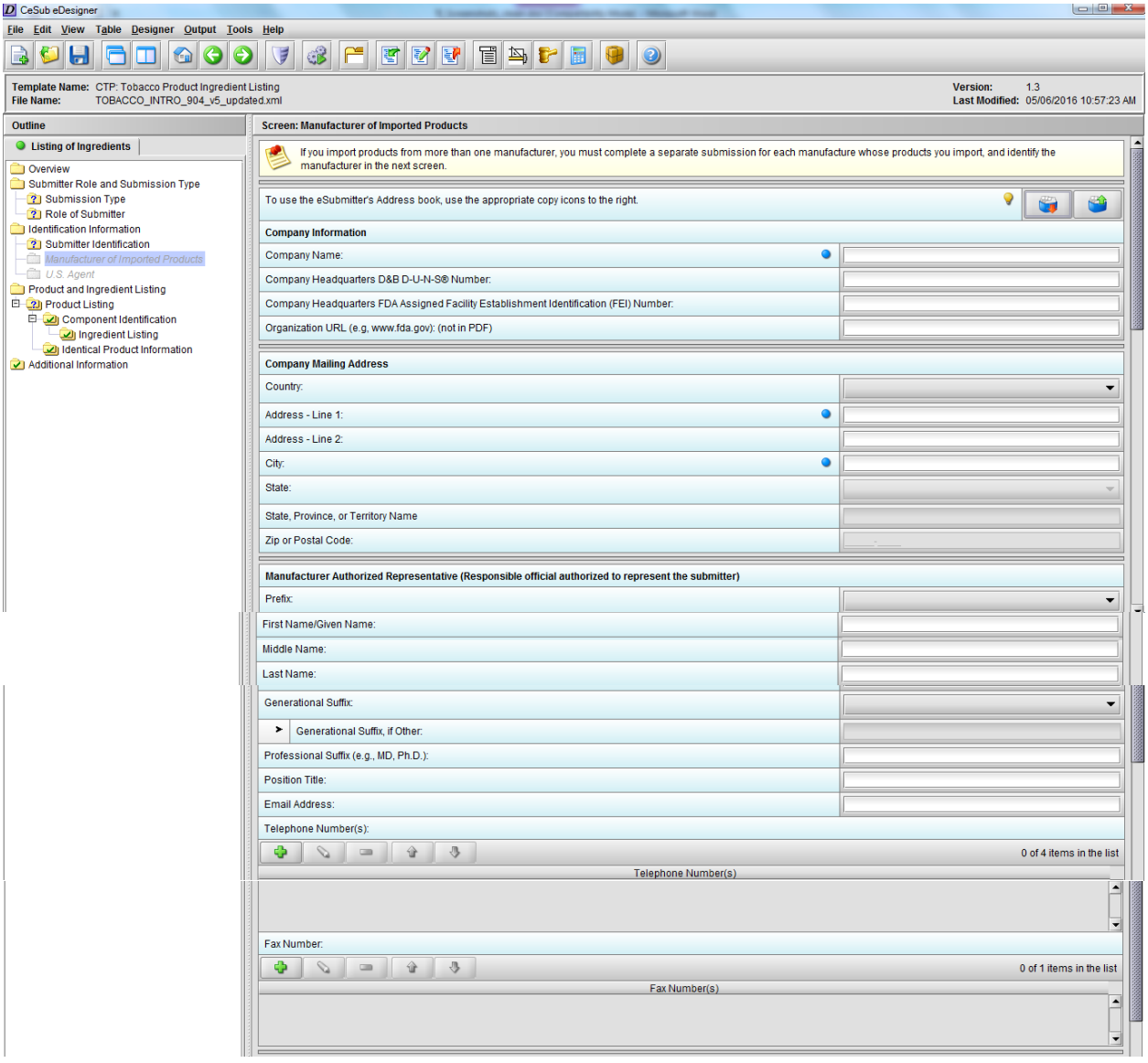
Additional Information
Screen: Submitter Identification
To use the eSubmitter's Address book, use the appropriate copy icons to the right.
Company Information
Company Name:
Company Headquarters D&B D-U-N-S® Number:
Company Headquarters FDA Assigned Facility Establishment Identification (FEI) Number:
Organization URL (e.g., www.fda.gov): (not in PDF)
Company Mailing Address:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:
Authorized Representative (Responsible official authorized to represent the submitter)
Prefix:
First Name/Given Name:
Middle Name:
Last Name:
Professional Suffix (e.g., MD, Ph.D.):
Position Title:
Email Address:
Telephone Number(s):
0 of 4 items in the list
Telephone Number(s)
Fax Number:
0 of 1 items in the list
Fax Number(s)


Mailing Address for the Authorized Representative (Responsible official authorized to represent the submitter)
Is the Manufacturer Point of Contact's Company Information the same as above?
Yes
No
Company Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
Zip or Postal Code:
OMB No. 0910-0650, Expiration Date: 5/31/2010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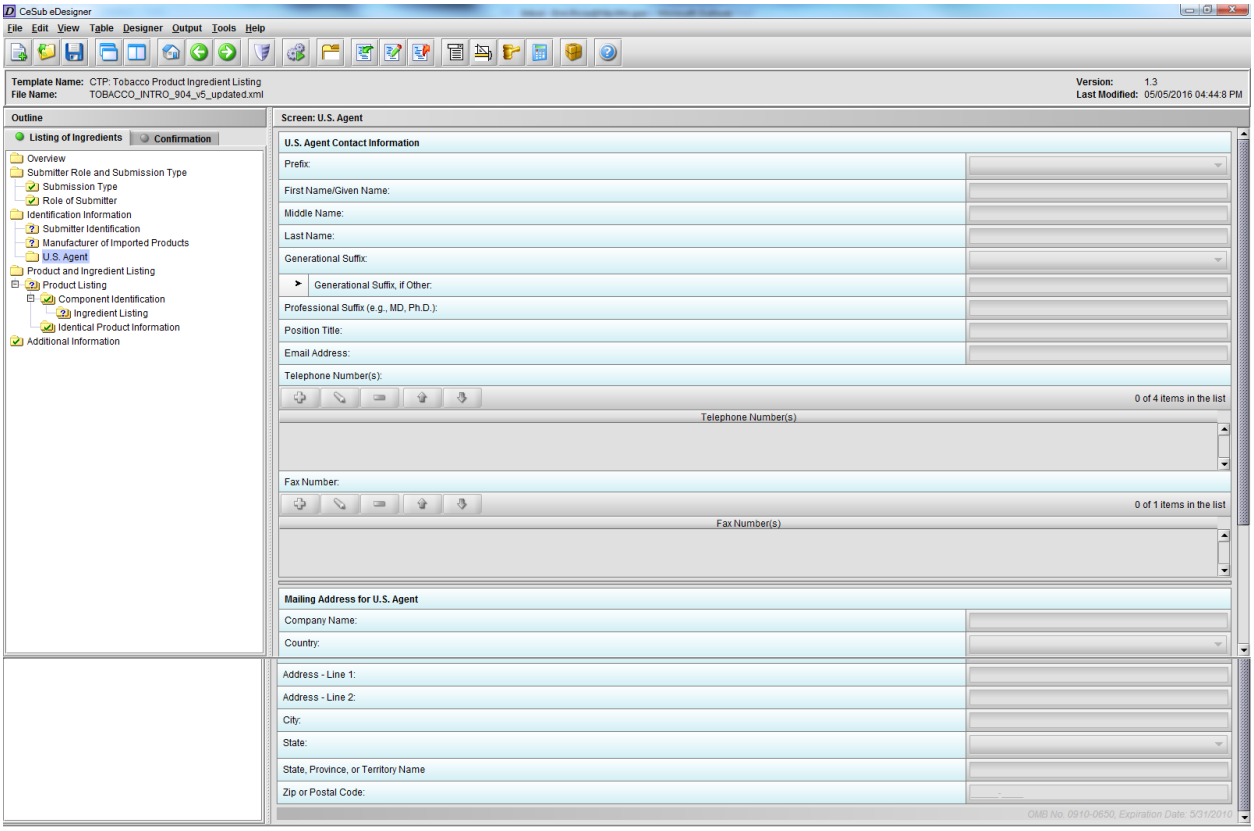
Identical Product Information
Additional Information
Screen: Manufacturer of Imported Products
If you import products from more than one manufacturer, you must complete a separate submission for each manufacture whose products you import, and identify the manufacturer in the next screen.
To use the eSubmitter's Address book, use the appropriate copy icons to the right.
Company Information
Company Name:
Company Headquarters D&B D-U-N-S® Number:
Company Headquarters FDA Assigned Facility Establishment Identification (FEI) Number:
Organization URL (e.g. www.fda.gov): (not in PDF)
Company Mailing Address
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:
Manufacturer Authorized Representative (Responsible official authorized to represent the submitter)
Prefix:
First Name/Given Name:
Middle Name:
Last Name:
Generational Suffix:
Generational Suffix, if Other:
Professional Suffix (e.g., MD, Ph.D.):
Position Title:
Email Address:
Telephone Number(s):
0 of 4 items in the list
Telephone Number(s)
Fax Number:
0 of 1 items in the list
Fax Number(s)


Mailing Address for Manufacturer Authorized Representative
Is the Importer Point of Contact's Company Information the same as above?
Yes
No
Company Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:


CeSub eDesigner
File Edit View Table Designer Output Tools Help
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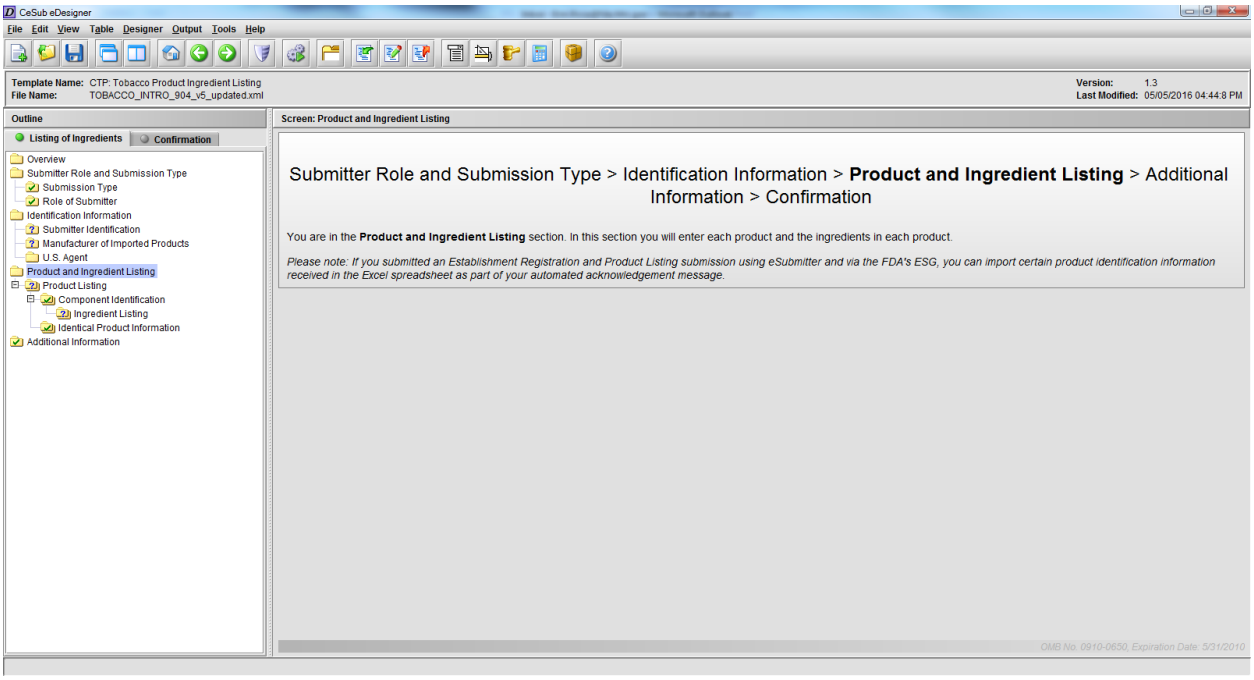
Ingredient Listing
Identical Product Information
Additional Information
Screen: U.S. Agent
U.S. Agent Contact Information
Prefix:
First Name/Given Name:
Middle Name:
Last Name:
Generational Suffix:
Generational Suffix, if Other:
Professional Suffix (e.g., MD, Ph.D.):
Position Title:
Email Address:
Telephone Number(s):
0 of 4 items in the list
Telephone Number(s)
Fax Number:
0 of 1 items in the list
Fax Number(s)
Mailing Address for U.S. Agent
Company Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code: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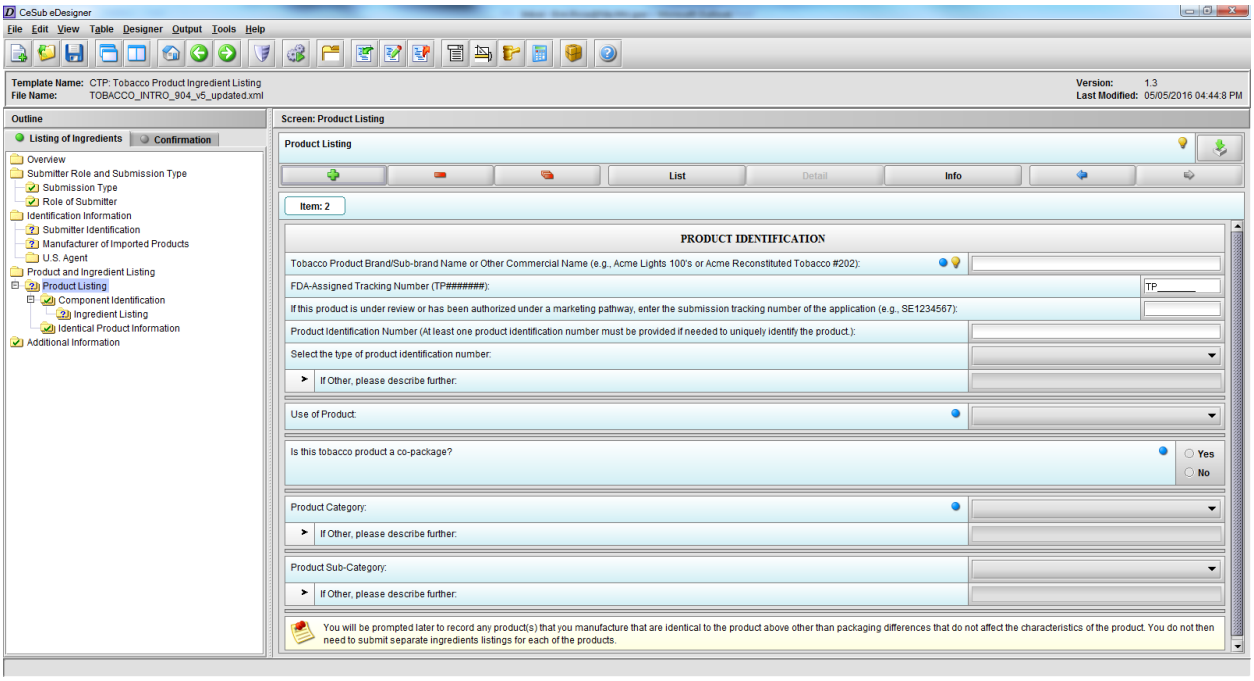
Additional Information
Screen: Product and Ingredient Listing
Submitter Role and Submission Type > Identification Information > Product and Ingredient Listing > Additional Information > Confirmation
You are in the Product and Ingredient Listing section. In this section you will enter each product and 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.
OMB No. 0910-0650, Expiration Date: 5/31/2010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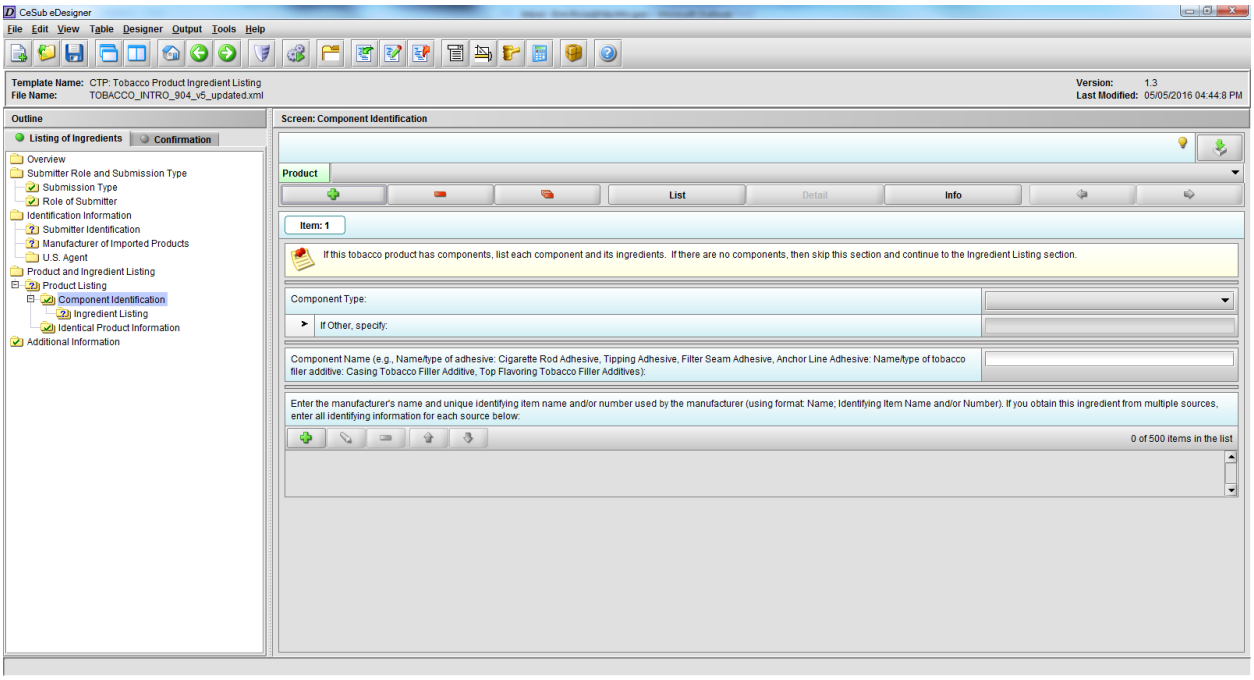
Screen: Product Listing
Product Listing
List
Detail
Info
Item: 2
PRODUCT IDENTIFICATION
Tobacco Product Brand/Sub-brand Name or Other Commercial Name (e.g., Acme Lights 100's or Acme Reconstituted Tobacco #202):
FDA-Assigned Tracking Number (TP########):
TP_____
If this product is under review or has been authorized under a marketing pathway, enter the submission tracking number of the application (e.g., SE1234567):
Product Identification Number (At least one product identification number must be provided if needed to uniquely identify the product.):
Select the type of product identification number:
If Other, please describe further:
Use of Product:
Is this tobacco product a co-package?
Yes
No
Product Category:
If Other, please describe further:
Product Sub-Category:
If Other, please describe further:
You will be prompted later to record any product(s) that you manufacture that are identical to the product above other than packaging differences that do not affect the characteristics of the product. You do not then need to submit separate ingredients listings for each of the products.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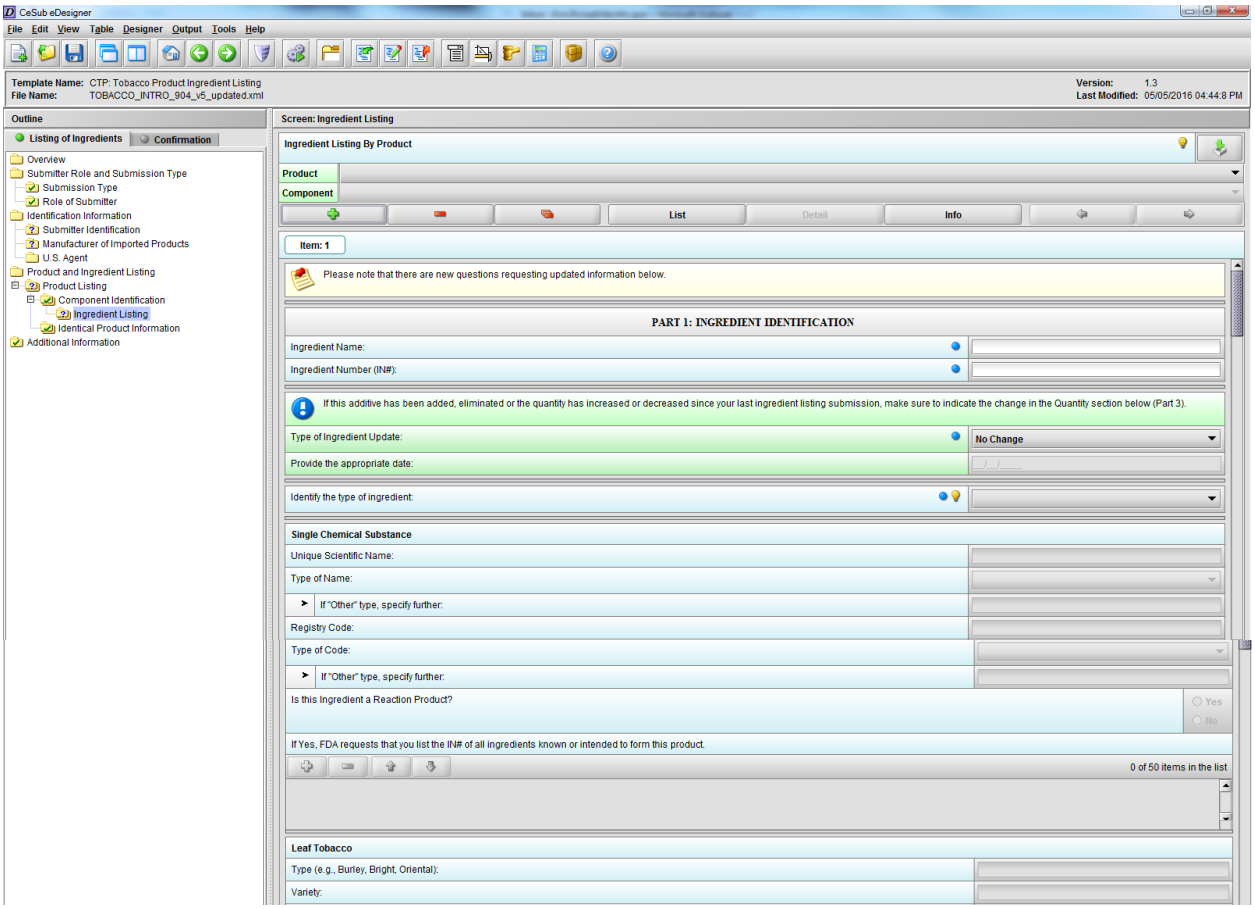
List
Detail
Info
Item: 1
If this tobacco product has components, list each component and its ingredients. If there are no components, then skip this section and continue to the Ingredient Listing section.
Component Type:
If Other, specify:
Component Name (e.g., Name/type of adhesive: Cigarette Rod Adhesive, Tipping Adhesive, Filter Seam Adhesive, Anchor Line Adhesive: Name/type of tobacco filler additive: Casing Tobacco Filler Additive, Top Flavoring Tobacco Filler Additives):
Enter the manufacturer's name and unique identifying item name and/or number used by the manufacturer (using format: Name; Identifying Item Name and/or Number). If you obtain this ingredient from multiple sources, enter all identifying information for each source below:
0 of 500 items in the list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Ingredient Listing By Product
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Component
List
Detail
Info
Item: 1
Please note that there are new questions requesting updated information below.
PART 1: INGREDIENT IDENTIFICATION
Ingredient Name:
Ingredient Number (IN#):
If this additive has been added, eliminated or the quantity has increased or decreased since your last ingredient listing submission, make sure to indicate the change in the Quantity section below (Part 3).
Type of Ingredient Update:
No Change
Provide the appropriate date:
Identify the type of ingredient:
Single Chemical Substance
Unique Scientific Name:
Type of Name:
If "Other" type, specify further:
Registry Code:
Type of Code:
If "Other" type, specify further:
Is this Ingredient a Reaction Product?
Yes
No
If Yes, FDA requests that you list the IN# of all ingredients known or intended to form this product.
0 of 50 items in the list
Leaf Tobacco
Type (e.g., Burley, Bright, Oriental):
Variety:

Cure Method:

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

Heat Source (e.g., propane, wood):

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

Complex Ingredients (e.g., flavor extracts, tobacco leaf blends, reconstituted tobacco, spices, fruit juice, adhesives, charcoal)

Enter the manufacturer's name and unique identifying item name and/or number used by the manufacturer (using format: Name; Identifying Item Name and/or Number). If you obtain this ingredient from multiple sources, enter all identifying information for each source below:

0 of 500 items in the list

Is this ingredient custom made to your specifications? ○ Yes ○ No

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

0 of 500 items in the list

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.

Quality - Unit of Measure:

If Other, please specify:

Quality Value:

Expected Function(s):

0 of 6 items in the list

If Other, please specify:

PART 3: QUANTITY

Add in Business Rules to make this section optional if Additive was Eliminated.

Unit of Measure:

Reported per:

Type of Quantity (select and complete associated fields below): Amount Calculated

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:

If Other, please specify:

Single Value:

Lower Limit:

Upper Limit:

Amount to Achieve an Outcome

Target Outcome Type: (MAY NEED BR TO ENSURE THIS SELECTION MATCHES VALUE/TYPE SELECTION)

If Other, please specify:

Target Outcome Units and Value(s):

If Other, please specify:

Value:

L* Value:

a* Value:

b* Value:

Select the reporting value for the quantity of the ingredient: ○ Typical Quantity ○ Range

Enter the typical quantity of the ingredient:

Enter the minimum quantity of the ingredient:

Enter the maximum quantity of the ingredient:

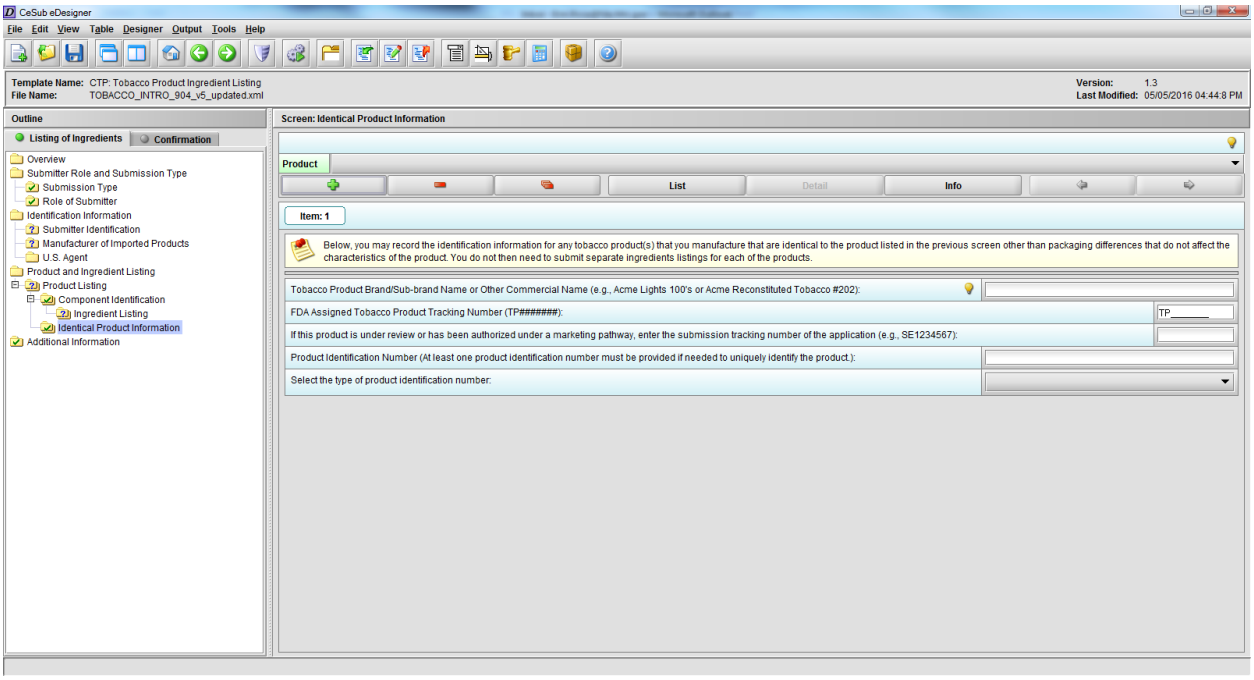
Residual Amount

Residual Quantity:

Limit of Detection:

PART 4: 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.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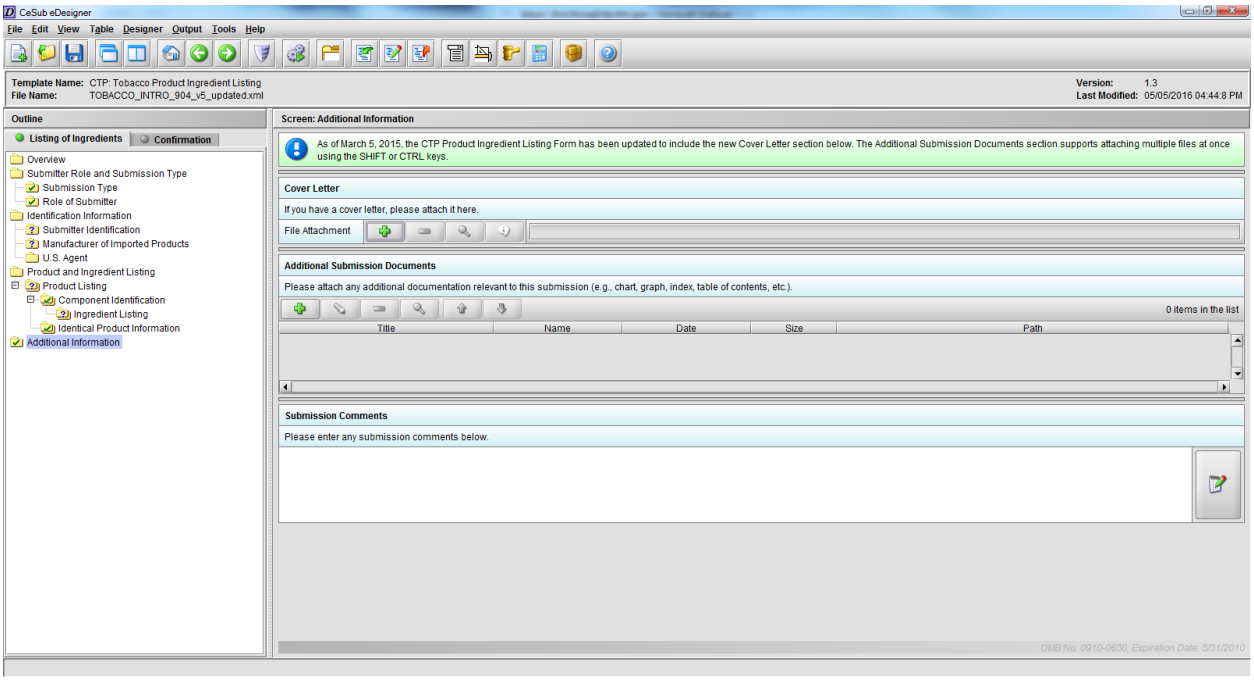
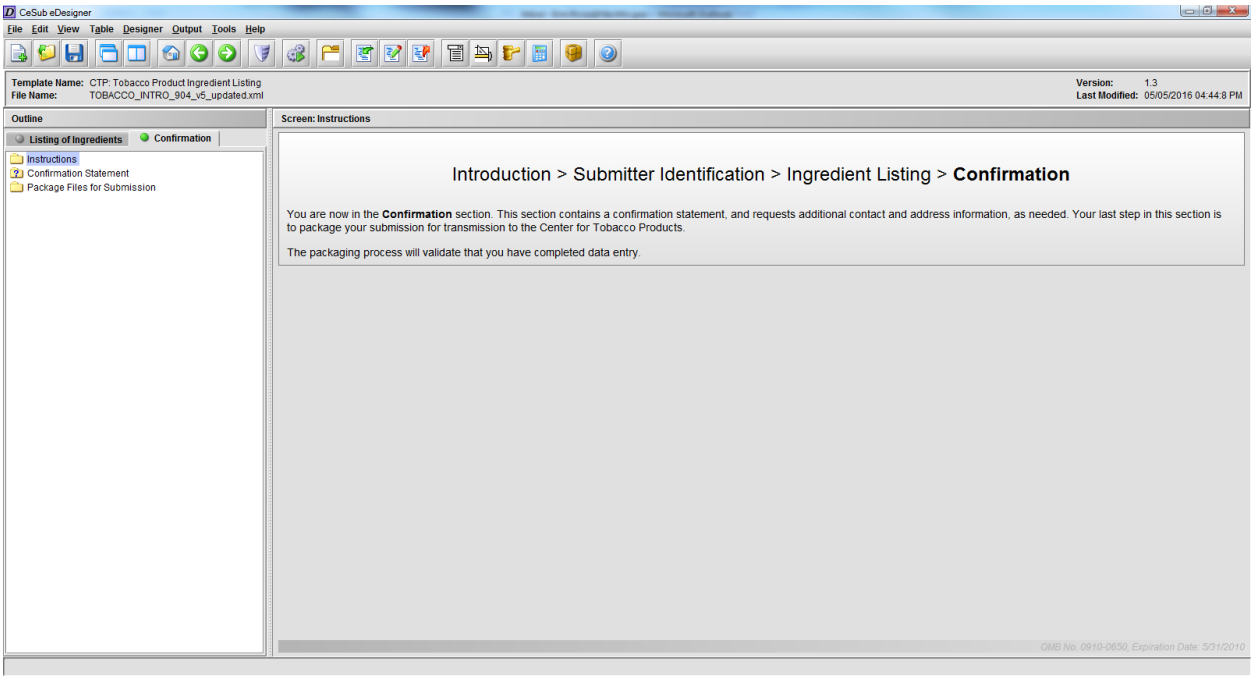
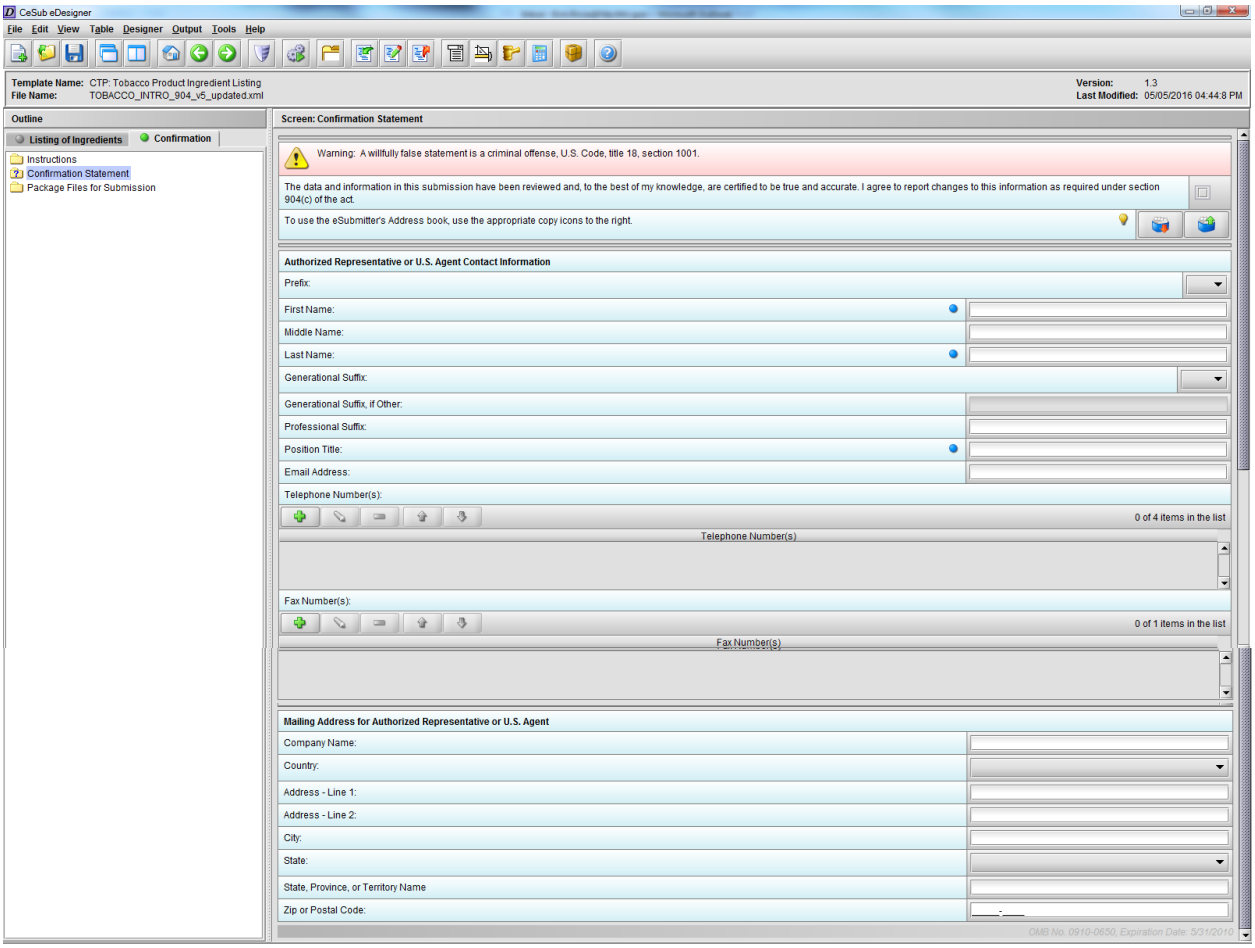
Submitter Identification
Manufacturer of Imported Products
U.S. Agent
Product and Ingredient Listing
Product Listing
Component Identification
Ingredient Listing
Identical Product Information
Additional Information
Screen: Identical Product Information
Product
List
Detail
Info
Item: 1
Below, you may record the identification information for any tobacco product(s) that you manufacture that are identical to the product listed in the previous screen other than packaging differences that do not affect the characteristics of the product. You do not then need to submit separate ingredients listings 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):
FDA Assigned Tobacco Product Tracking Number (TP#######):
TP_____
If this product is under review or has been authorized under a marketing pathway, enter the submission tracking number of the application (e.g., SE1234567):
Product Identification Number (At least one product identification number must be provided if needed to uniquely identify the product.):
Select the type of product identification number:


CeSub eDesigner
File Edit View Table Designer Output Tools Help
Template Name: CTP: Tobacco Product Ingredient Listing
File Name: TOBACCO_INTRO_904_v5_updated.xml
Version: 1.3
Last Modified: 05/05/2016 04:44:8 PM
Outline
Listing of Ingredients
Confirmation
Overview
Submitter Role and Submission Type
Submission Type
Role of Submitter
Identification Information
Submitter Identification
Manufacturer of Imported Products
U.S. Agent
Product and Ingredient Listing
Product Listing
Component Identification
Ingredient Listing
Identical Product Information
Additional Information
Screen: Additional Information
As of March 5, 2015, the CTP Product Ingredient Listing Form has been updated to include the new Cover Letter section below. The Additional Submission Documents section supports attaching multiple files at once using the SHIFT or CTRL keys.
Cover Letter
If you have a cover letter, please attach it here.
File Attachment
Additional Submission Documents
Please attach any additional documentation relevant to this submission (e.g., chart, graph, index, table of contents, etc.).
0 items in the list
Title
Name
Date
Size
Path
Submission Comments
Please enter any submission comments below.
OMB No. 0910-0650, Expiration Date: 5/31/2010


CeSub eDesigner
File Edit View Table Designer Output Tools Help
Template Name: CTP: Tobacco Product Ingredient Listing
File Name: TOBACCO_INTRO_904_v5_updated.xml
Version: 1.3
Last Modified: 05/05/2016 04:44:8 PM
Outline
Listing of Ingredients
Confirmation
Instructions
Confirmation Statement
Package Files for Submission
Screen: Instructions
Introduction > Submitter Identification > Ingredient 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.
OMB No. 0910-0650, Expiration Date: 5/31/2010


CeSub eDesigner
File Edit View Table Designer Output Tools Help
Template Name: CTP: Tobacco Product Ingredient Listing
File Name: TOBACCO_INTRO_904_v5_updated.xml
Version: 1.3
Last Modified: 05/05/2016 04:44:8 PM
Outline
Listing of Ingredients
Confirmation
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(c) of the act.
To use the eSubmitter's Address book, use the appropriate copy icons to the right.
Authorized Representative or U.S. Agent Contact Information
Prefix:
First Name:
Middle Name:
Last Name:
Generational Suffix:
Generational Suffix, if Other:
Professional Suffix:
Position Title:
Email Address:
Telephone Number(s):
0 of 4 items in the list
Telephone Number(s)
Fax Number(s):
0 of 1 items in the list
Fax Number(s)
Mailing Address for Authorized Representative or U.S. Agent
Company Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:
OMB No. 0910-0650, Expiration Date: 5/31/2010