

eSubmitter v3
CTP Tobacco Product Manufacturer form

Menu Options

- Create New Submission...
- Open Existing Submission...
- eSubmitter Quick Guide...
- Exit Application

Messages

Welcome | Alerts and News | Helpful Tips | Addresses and Contacts | Links | Frequently Asked Questions | History

Welcome to eSubmitter! An FDA Electronic Submissions Software Initiative

Overview: This software application enables electronic submission of regulatory information to FDA in an effort to automate the submission process. It contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses, and to allow FDA to capture data in a more useful, structured format. These benefits enable Centers within the FDA to improve our review process and reduce lengthy review times.

Getting Started: To familiarize yourself with the eSubmitter application, see the "Getting Started" section of the "eSubmitter Quick Guide", which provides layout information as well as tips for navigating the Intro screen. In addition, the "eSubmitter Quick Guide" also provides information on creating a new submission through to the submission packaging process. The "eSubmitter Quick Guide" can be launched from the corresponding menu option on the left-hand side of this Intro screen.

Contact Us: Please email any questions or comments concerning this software application to the eSubmitter team at: esubmitter@fda.hhs.gov. Please be sure to include your name, company name and contact information in the email. Otherwise, for Regulatory questions, contact the appropriate office. See [Addresses and Contacts](#) for further details.

Application Updates: Updates in this software are automatic. These updates will occur, as available, if you are logged onto the Internet at the time that the application is launched.

Thank you again for us

Create New Submission

Step 1 Select Submission Type

List of Available Submission Types

Name	Version	Version Date	Last Create Date	Last Submit Date
CDRH: Radiation Emitting Product (OMB NO. 0910-0025)	2.6	12/03/2019 11:53:3 PM		
CDRH: Radiation Emitting Product (OMB NO. 0910-0025)	2.6.1	08/18/2020 04:03:15 PM		
CDRH: Report of Assembly of a Diagnostic X-Ray System	1.4.1	08/12/2021 02:20:15 PM		
CTP: Tobacco 904(a)(3) Template	1.8	10/03/2019 12:26:18 PM		
CTP: Tobacco Health/Requested Document Submission	1.1	09/05/2020 10:27:15 AM		
CTP: Tobacco Product Ingredient Listing	2.9	10/04/2019 01:32:45 PM		
CTP: Transmittal Form	2.2	10/03/2019 12:29:23 PM		

Description of Selected Submission Type

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 \(Pub. Law 111-31\)](#).

For your reference, see the [Guidance: Listing of Ingredients in Tobacco Products](#).

Version: 3.54.00 Build 1
Last Updated: 05/05/2022

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

Department of Health & Human Services

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 software interface. The main window has a menu bar (File, Edit, View, Table, Output, Tools, Help) and a toolbar. The left sidebar contains 'Menu Options' with buttons for 'Create New Submission...', 'Open Existing Submission...', 'eSubmitter Quick Guide...', and 'Exit Application'. The main content area shows a 'Welcome to eSubmitter! An FDA Electronic Submissions Software Initiative' message with an overview, getting started, and contact us section. A 'New Submission Dialog' is open, showing 'Step 2: Provide Submission Details'. This dialog includes fields for 'Descriptive Name' and 'File Name (.xml)', both containing the text 'Test'. There is also a text area for 'Additional Comments about this Submission' with the text 'Test'. At the bottom of the dialog are 'Cancel', 'Previous', 'Next', and 'Create' buttons. The 'Create' button is highlighted with a red box. The footer of the software shows 'FDA U.S. Food and Drug Administration' and 'Department of Health & Human Services'.

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area is titled "Listing of Ingredients: Overview" and contains the following text:

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 xx/xx/xxxx)

Blue dots indicate required fields.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner of the window, the text "OMB No. 0910-0650, Expiration Date: 3/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar below the menu bar contains various icons for file operations and navigation. The main content area is divided into two tabs: "Listing of Ingredients" (active) and "Confirmation". The "Listing of Ingredients" tab is further divided into "Overview" and "Confirmation" sub-sections. The "Overview" sub-section is expanded, showing a tree view of the submission structure:

- 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

At the bottom of the window, there are two buttons: "Screen View" (highlighted with a red box) and "Select".

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test16
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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. 0919-0650, Expiration Date: 5/31/2010

Previous Step Outline View Next Step

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test16
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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:

DMB No. 0910-0650, Expiration Date: 3/31/2010

Previous Outline View Next

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 web application interface. At the top, there is a menu bar with 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. Below the menu bar is a toolbar with various icons for file operations. The main content area is titled 'Submission Type' and contains the following text:

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:

At the bottom of the interface, there are navigation buttons: a left arrow, 'Outline View', and a right arrow. The right arrow button is highlighted with a red box. In the bottom right corner, the text 'OMB No. 0910-0630, Expiration Date: 5/31/2010' is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test16
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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: 3/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test16
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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. 0910-0630, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar features icons for file operations and navigation. The main content area is titled "Listing of Ingredients: Identification Information" and contains a breadcrumb trail: "Submitter Role and Submission Type > Identification Information > Product and Ingredient Listing > Additional Information > Confirmation". Below the breadcrumb, a message states: "You are in the **Submitter Identification** section. This section requests contact and address information for the responsible individual submitting the Ingredient Listing submission." The bottom of the window features a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. A red box highlights the right arrow. In the bottom right corner, the text "OMB No: 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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):

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:

Generational Suffix:

Generational Suffix, if Other:

Professional Suffix (e.g., MD, Ph.D.):

Position Title:

Email Address:

Telephone Number(s):

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: U.S. Agent

To use the eSubmitter's Address book, use the appropriate copy icons to the right

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:

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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: You can import Product and Ingredient information by populating data onto the import Excel spreadsheet templates. The import spreadsheet templates can be found under the Info button on the respective Product and Ingredient screens. They can be accessed by clicking the "Import Spreadsheet Template" link under the Import Method section.

How will you provide Product, Component, Ingredient, and Identical Product Information?

- a) Enter product, component, and ingredient information manually on the following screens
- b) Enter product and ingredient information using separate CTP-provided spreadsheets, and enter component information manually
- c) Attach product, component, and ingredient information using a single CTP-provided spreadsheet
- d) Attach your own spreadsheet

Further instructions will appear in this section upon selection of a response to the above question.

Import Method for E-Liquid Products:
Click on the link ([Listing of Ingredients in Tobacco E-Liquid Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Leaf-Wrapped Cigar Products:
Click on the link ([Listing of Ingredients in Tobacco Leaf-Wrapped Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Ingredients in any Tobacco Product:
Click on the link ([Listing of Ingredients in Any Tobacco Product](#)) to launch the pre-formatted Excel spreadsheet.

Attach the Product, Component, Ingredient spreadsheet

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Outline View

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The header area shows "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". On the right, it indicates "Last Modified:" and "Date Packaged:". The main content area is titled "Listing of Ingredients: Product Listing" and contains the following text:

Product Listing

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.

At the bottom of the screen, there is a navigation bar with buttons for "Previous", "Outline View", and "Next". The "Next" button is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The main content area is titled "Listing of Ingredients: Product Listing" and contains instructions on how to enter product data, including sections for "Data Entry Method" and "Import Method". A "List Data Message Dialog" is overlaid on the screen, with the following text:

List Data Message Dialog

Select an option

- I would like to add another Product
- I am finished entering Product(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

Buttons: OK, Cancel

At the bottom of the application window, there are navigation buttons: "Back", "Outline View", and "Next Screen". The "Next Screen" button is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The status bar at the top shows "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". The main content area is titled "Listing of Ingredients: Product Listing" and contains the following text:

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 spreadsheet.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the information.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and exporting data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the spreadsheet.
5. After all data is imported, you can click on the "List" button to view and verify the imported product information.

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

The "List Data Message Dialog" is a modal window with the following elements:

- Title: List Data Message Dialog
- Text: Select an option
- Radio buttons:
 - I would like to add another Product
 - I am finished entering Product(s) and I would like to move to the next screen
- Checkbox: Ignore future add/navigation messages when exiting list screens?
- Buttons: OK, Cancel

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 1

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#####):

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?

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 1

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#####):

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?

Product Category:

If Other, please describe further:

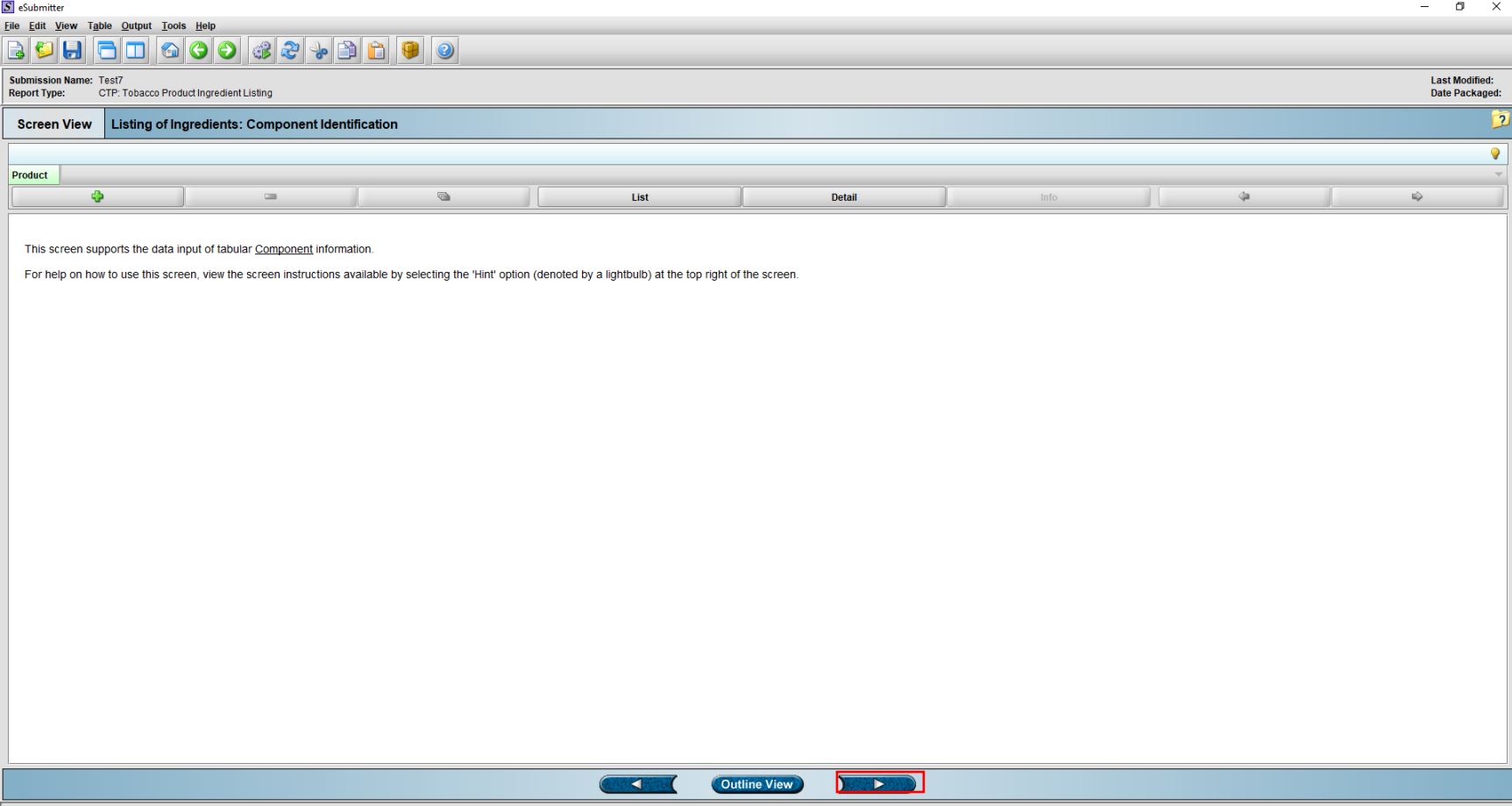
Product Sub-Category:

If Other, please describe further:

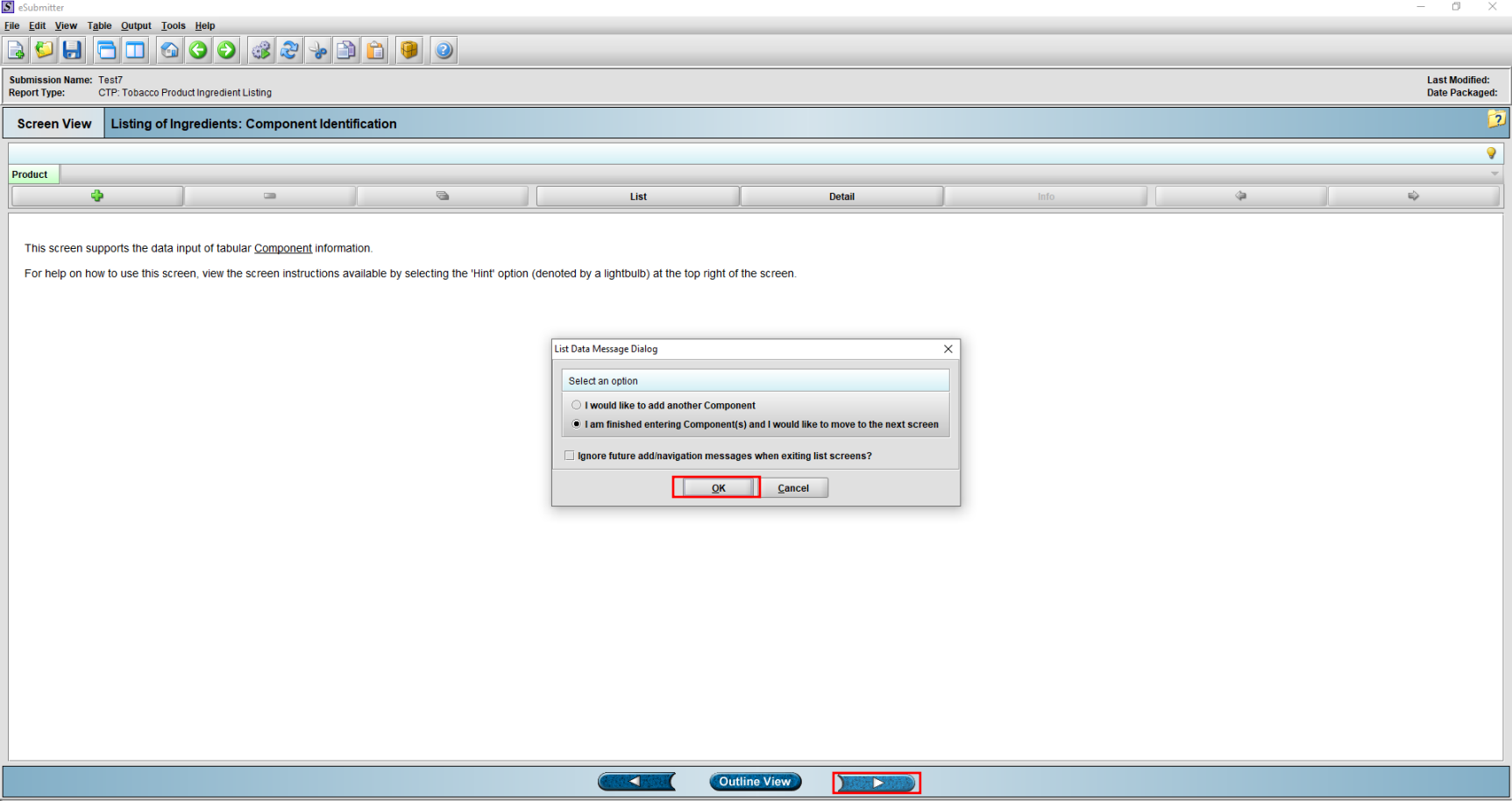
You will be prompted later to record any product(s) that you manufacture that are identical to the product above other than packaging differences that do not affect the characteristics of the product. You do not then need to submit separate ingredients listings for each of the products.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3

CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

Outline View

eSubmitter v3 CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main window area shows the "Listing of Ingredients: Ingredient Listing" screen. At the top, it displays "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". Below this, there are tabs for "Screen View" and "Listing of Ingredients: Ingredient Listing". The main content area is titled "Ingredient Listing By Product" and contains a table with columns for "Product" and "Component". Below the table, there are buttons for "List", "Detail", and "Info". A "List Data Message Dialog" is open in the center, with the following text: "List Data Message Dialog", "Select an option", "I would like to add another Ingredient", "I am finished entering ingredient(s) and I would like to move to the next screen", and "Ignore future add/navigation messages when exiting list screens?". The "OK" button is highlighted with a red box. The background screen contains instructions on how to enter ingredient information and a navigation bar with an "Outline View" button also highlighted with a red box.

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button.
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 advance to this screen to add the ingredient information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet import button.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the spreadsheet.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and exporting data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the spreadsheet.
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.

[Identification Updates](#) to launch the pre-formatted Excel spreadsheet for the import process.

Import wizard.

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 validation of the data.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

Outline View

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main content area is titled 'Listing of Ingredients: Product Listing' and features a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. Below this is a 'Table of Tobacco Products' with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. The table contains one row with 'Item' value '1'. At the bottom of the table area, it says '1 of 9999 Items in the list'. The 'Outline View' button at the bottom center is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. A status bar at the top right shows 'Last Modified:' and 'Date Packaged:'. The current screen is 'Listing of Ingredients: Product Listing'. Below this is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is visible, with columns for Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. A dialog box titled 'List Data Message Dialog' is open, asking the user to 'Select an option' with two radio buttons: 'I would like to add another Product' and 'I am finished entering Product(s) and I would like to move to the next screen'. There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the application, there are navigation buttons: 'Previous Screen', 'Outline View', and 'Next Screen', with the 'Next Screen' button also highlighted with a red box. A status bar at the bottom indicates '1 of 9999 items in the list'.

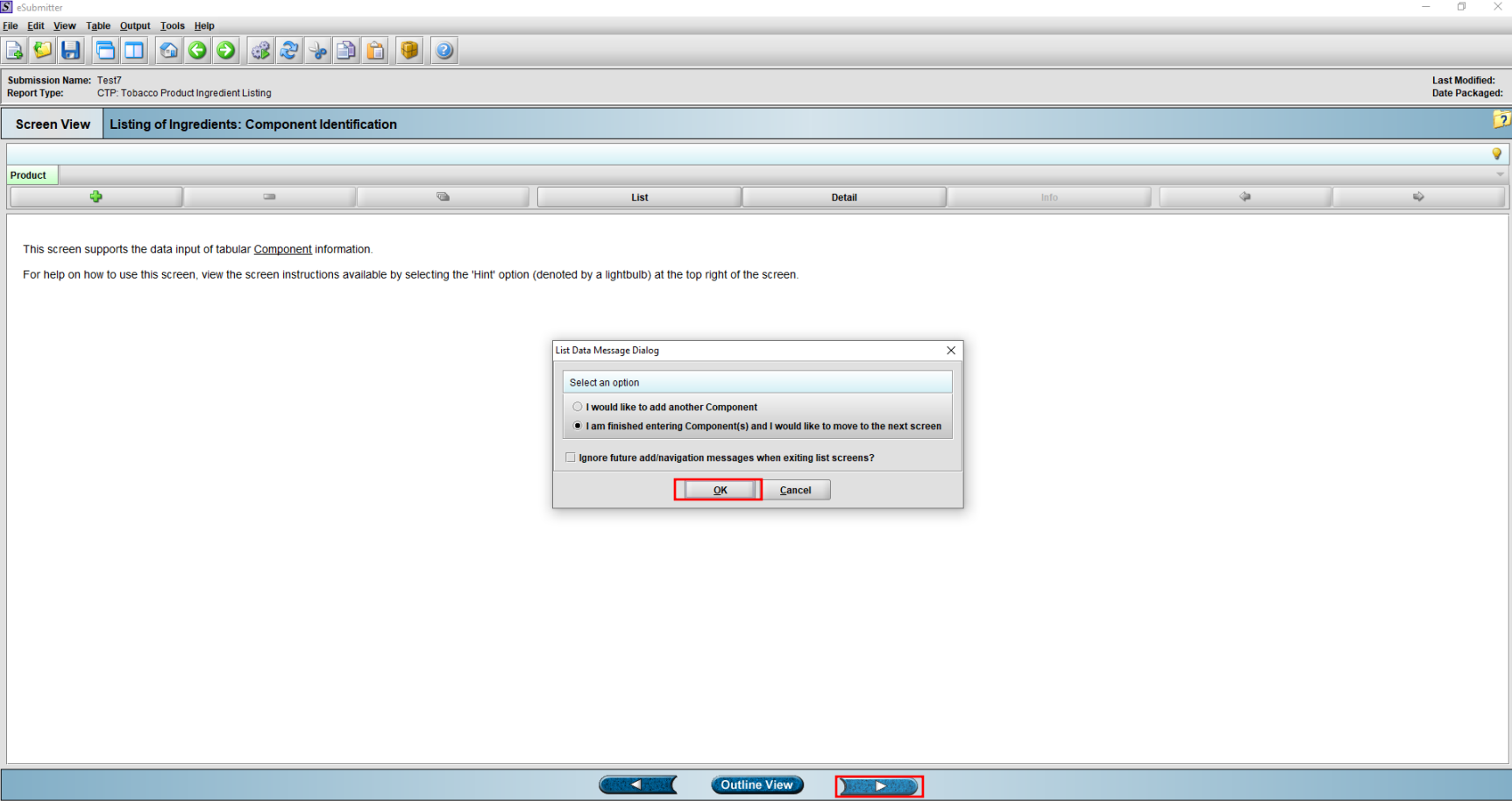
eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main content area is titled 'Listing of Ingredients: Component Identification' and features a 'Product' tab. Below the tab is a navigation bar with buttons for 'List', 'Detail', and 'Info'. The main area contains the following text:

This screen supports the data input of tabular Component information.
For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow button is highlighted with a red rectangle.

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The status bar at the top right shows "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". The main content area is titled "Listing of Ingredients: Ingredient Listing" and contains the following text:

Ingredient Listing By Product

Product

Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

At the bottom of the window, there is a navigation bar with buttons for "List", "Detail", "Info", and "Outline View". The "Outline View" button is highlighted with a red box.

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button.
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 add the Ingredient information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet import button.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the spreadsheet.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and exporting data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the spreadsheet.
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.

List Data Message Dialog

Select an option

I would like to add another ingredient

I am finished entering ingredient(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

OK Cancel

Outline View

eSubmitter v3

CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View | Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to enter information on 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 add the product information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation process.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right of the spreadsheet.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

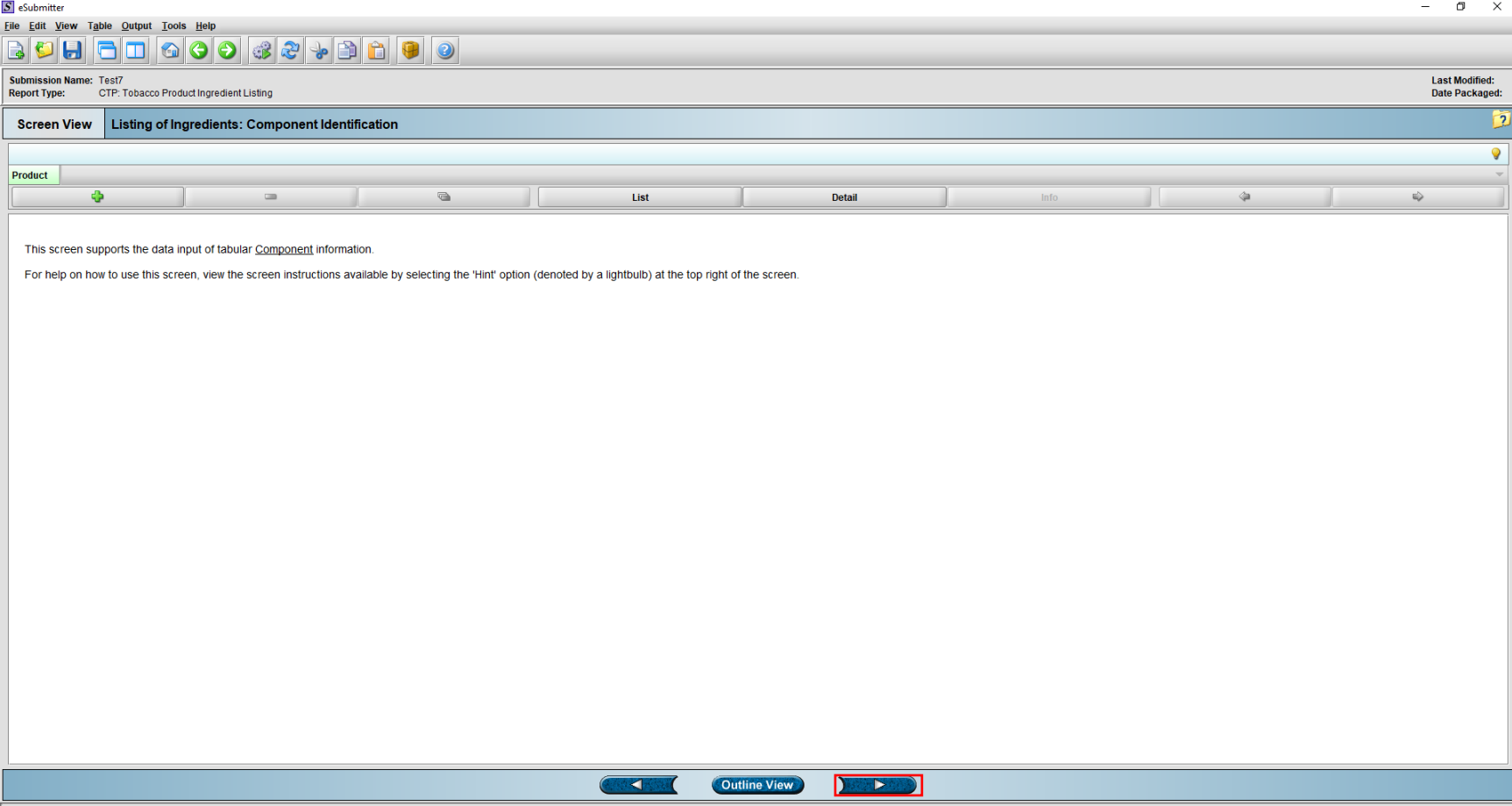
the List and advance to this screen to add the Ingredient information.

[Click here for Ingredient Identification Updates](#) to launch the pre-formatted Excel spreadsheet. Save the file during the import process.

Follow the import wizard.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The status bar at the top shows "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". The main content area is titled "Listing of Ingredients: Component Identification" and contains a "Product" tab and a "List" button. A "List Data Message Dialog" box is open, asking the user to "Select an option" with two radio buttons: "I would like to add another Component" and "I am finished entering Component(s) and I would like to move to the next screen". The "OK" button in the dialog is highlighted with a red box. At the bottom of the application window, the "Outline View" button is also highlighted with a red box.

eSubmitter v3

CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

Outline View

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window content shows the 'Listing of Ingredients: Ingredient Listing' screen. At the top, it displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. Below this, there are tabs for 'Screen View' and 'Listing of Ingredients: Ingredient Listing'. The main area is titled 'Ingredient Listing By Product' and contains a table with columns for 'Product' and 'Component'. Below the table, there are buttons for 'List', 'Detail', and 'Info'. A 'List Data Message Dialog' is open in the center, with the following text: 'List Data Message Dialog', 'Select an option', 'I would like to add another ingredient', 'I am finished entering ingredient(s) and I would like to move to the next screen', and 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button in the dialog is highlighted with a red box. At the bottom of the application window, there are navigation buttons, including 'Outline View' and a 'Next Screen' button, which is also highlighted with a red box.

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to enter information on 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 select the product.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
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 of the spreadsheet.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

the List and advance to this screen to add the Ingredient information.

[Click here for Ingredient Identification Updates](#) to launch the pre-formatted Excel spreadsheet. Save the file during the import process.

Follow the import wizard.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Additional Information

If you used a spreadsheet to import product and ingredient data, you may attach it to the Additional Submission Documents attachment question.

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., Import Spreadsheet template for Product Identification, chart, graph, index, table of contents, etc.).

0 items in the list

Title	Name	Date	Size	Path
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Submission Comments
Please enter any submission comments below.

OMB No. 0910-0650, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area shows the following information:

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View | Confirmation: 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. 0910-0630, Expiration Date: 5/31/2010

Navigation buttons at the bottom include a left arrow, "Outline View", and a right arrow (highlighted with a red box).

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main window displays the "Confirmation: Confirmation Statement" section, which is highlighted in blue. A warning message is visible at the top: "Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001." Below this, a text box contains the 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." The form includes fields for "Identify the person submitting this form:" and "To use the eSubmitter's Address book, use the appropriate copy icons to the right." The "Contact Information" section contains fields for Prefix, First Name, Middle Name, Last Name, Generational Suffix, Generational Suffix, if Other, Professional Suffix, Position Title, Email Address, and Telephone Number(s). The Telephone Number(s) field shows "0 of 4 items in the list" and the Fax Number(s) field shows "0 of 1 items in the list". The "Mailing Address" section is partially visible at the bottom. The navigation bar at the bottom of the form includes buttons for "Previous", "Outline View", and "Next", with the "Next" button highlighted by a red rectangle.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area is titled "Confirmation: Package Files for Submission" and contains the following text:

STOP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red rectangle. In the bottom right corner of the window, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains icons for file operations and navigation. The main window header shows "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". On the right, it indicates "Last Modified:" and "Date Packaged:". The main content area is titled "Confirmation: Package Files for Submission" and contains a "STOP" icon and the following text:

You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

A "Warning" dialog box is open in the center of the screen, containing the following text:

You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses.

The dialog box has a "Close" button. At the bottom of the application window, there is a navigation bar with a left arrow, an "Outline View" button, and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner of the application window, the text "OMB No: 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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](#).

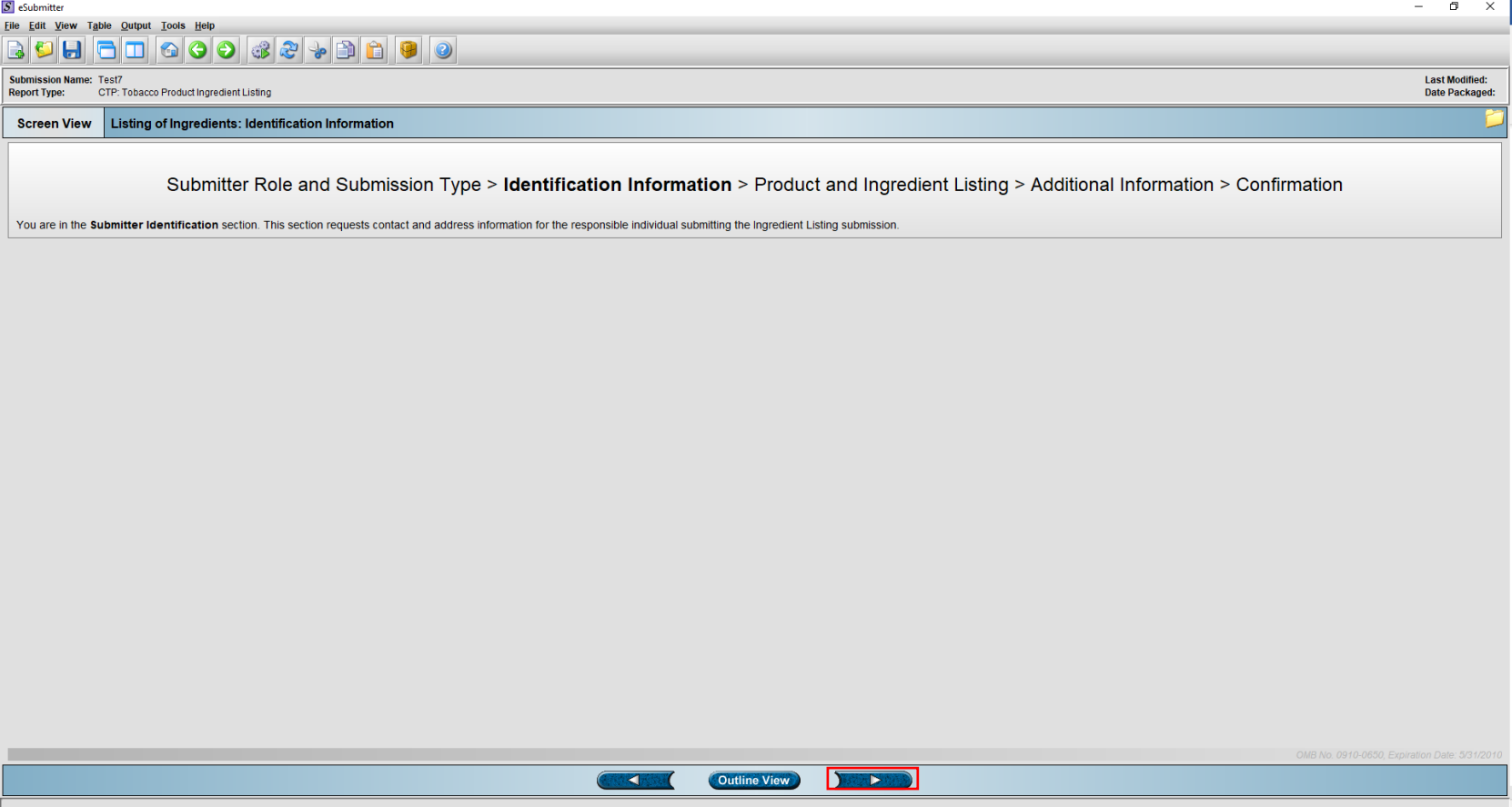
Please identify your role:

Manufacturer
 Importer

OMB No. 0910-0650, Expiration Date: 5/31/2010

Previous Outline View Next

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The status bar at the top right shows "Last Modified:" and "Date Packaged:". The main content area is titled "Listing of Ingredients: Submitter Identification".

Company Information

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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):

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:

Generational Suffix:

Generational Suffix, if Other:

Professional Suffix (e.g., MD, Ph.D.):

Position Title:

Email Address:

Telephone Number(s):

At the bottom of the form, there are navigation buttons: a left arrow, a button labeled "Outline View", and a right arrow. The "Outline View" button is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter
File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View **Listing of Ingredients: U.S. Agent**

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

U.S. Agent Contact Information

Prefix: [Dropdown]
First Name/Given Name: [Text]
Middle Name: [Text]
Last Name: [Text]
Generational Suffix: [Dropdown]
Generational Suffix, if Other: [Text]
Professional Suffix (e.g., MD, Ph.D.): [Text]
Position Title: [Text]
Email Address: [Text]
Telephone Number(s): [List] 0 of 4 items in the list
Fax Number: [List] 0 of 1 items in the list

Mailing Address for U.S. Agent

Company Name: [Text]
Country: [Dropdown] United States
Address - Line 1: [Text]
Address - Line 2: [Text]
City: [Text]

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View **Listing of Ingredients: 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: You can import Product and Ingredient information by populating data onto the import Excel spreadsheet templates. The import spreadsheet templates can be found under the Info button on the respective Product and Ingredient screens. They can be accessed by clicking the "Import Spreadsheet Template" link under the Import Method section.

How will you provide Product, Component, Ingredient, and Identical Product information?

- a) Enter product, component, and ingredient information manually on the following screens
- b) Enter product and ingredient information using separate CTP-provided spreadsheets, and enter component information manually
- c) Attach product, component, and ingredient information using a single CTP-provided spreadsheet
- d) Attach your own spreadsheet

Further instructions will appear in this section upon selection of a response to the above question.

Import Method for E-Liquid Products:
Click on the link ([Listing of Ingredients in Tobacco E-Liquid Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Leaf-Wrapped Cigar Products:
Click on the link ([Listing of Ingredients in Tobacco Leaf-Wrapped Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Ingredients in any Tobacco Product:
Click on the link ([Listing of Ingredients in Any Tobacco Product](#)) to launch the pre-formatted Excel spreadsheet.

Attach the Product, Component, Ingredient spreadsheet.

Title	Name	Date	Size	Path
0 items in the list				

Navigation buttons: Previous, Outline View, Next (highlighted with a red box)

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays the following information:

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View: Listing of Ingredients: Product Listing

Product Listing

Table of Tobacco Products

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, if Other	Product Use	Co-Package?	Product Category
>	1									

1 of 9999 items in the list

Navigation buttons: Previous Page, Outline View, Next Page (highlighted with a red box).

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The 'Screen View' is 'Listing of Ingredients: Product Listing'. Below this is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is visible, with columns for Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. A 'List Data Message Dialog' box is open in the center, asking the user to select an option: 'I would like to add another Product' (unselected) or 'I am finished entering Product(s) and I would like to move to the next screen' (selected). There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the application, there are navigation buttons: a left arrow, 'Outline View', and a right arrow, with the right arrow button also highlighted with a red box. The status bar at the bottom indicates '1 of 9999 items in the list'.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. A status bar at the top right shows 'Last Modified:' and 'Date Packaged:'. The current screen view is 'Listing of Ingredients: Product Listing'. Below this, there is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is visible, with columns for Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. A 'List Data Message Dialog' is open in the center, asking the user to 'Select an option' with two radio buttons: 'I would like to add another Product' (selected) and 'I am finished entering Product(s) and I would like to move to the next screen'. There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The dialog has 'OK' and 'Cancel' buttons. At the bottom of the application, there are navigation buttons for 'Previous', 'Outline View', and 'Next', with the 'Next' button highlighted by a red box. A status bar at the bottom indicates '1 of 9999 items in the list'.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

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#####):

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?

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View Listing of Ingredients: Product Listing

Product Listing

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#####):

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:

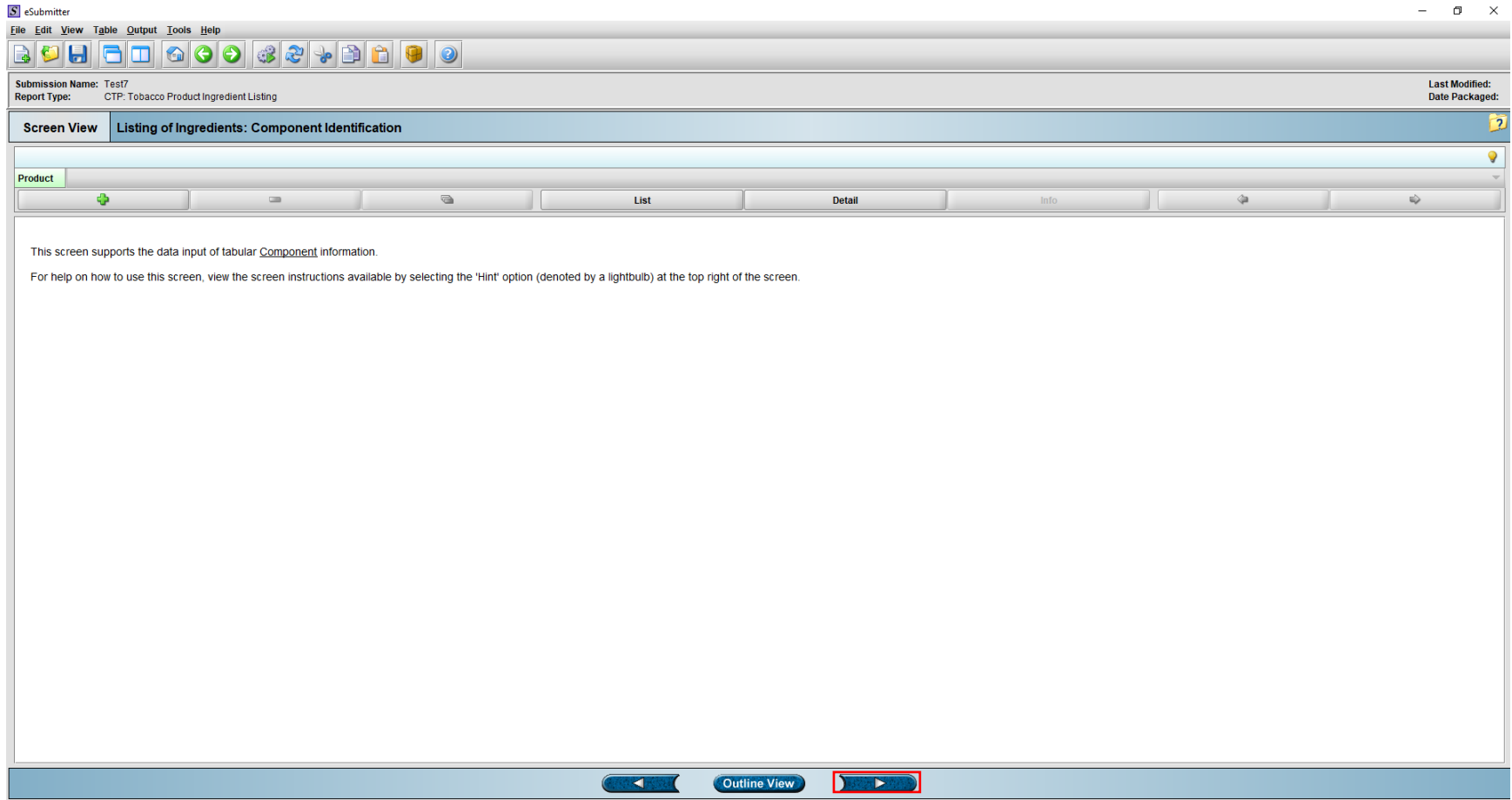
Product Sub-Category:

If Other, please describe further:

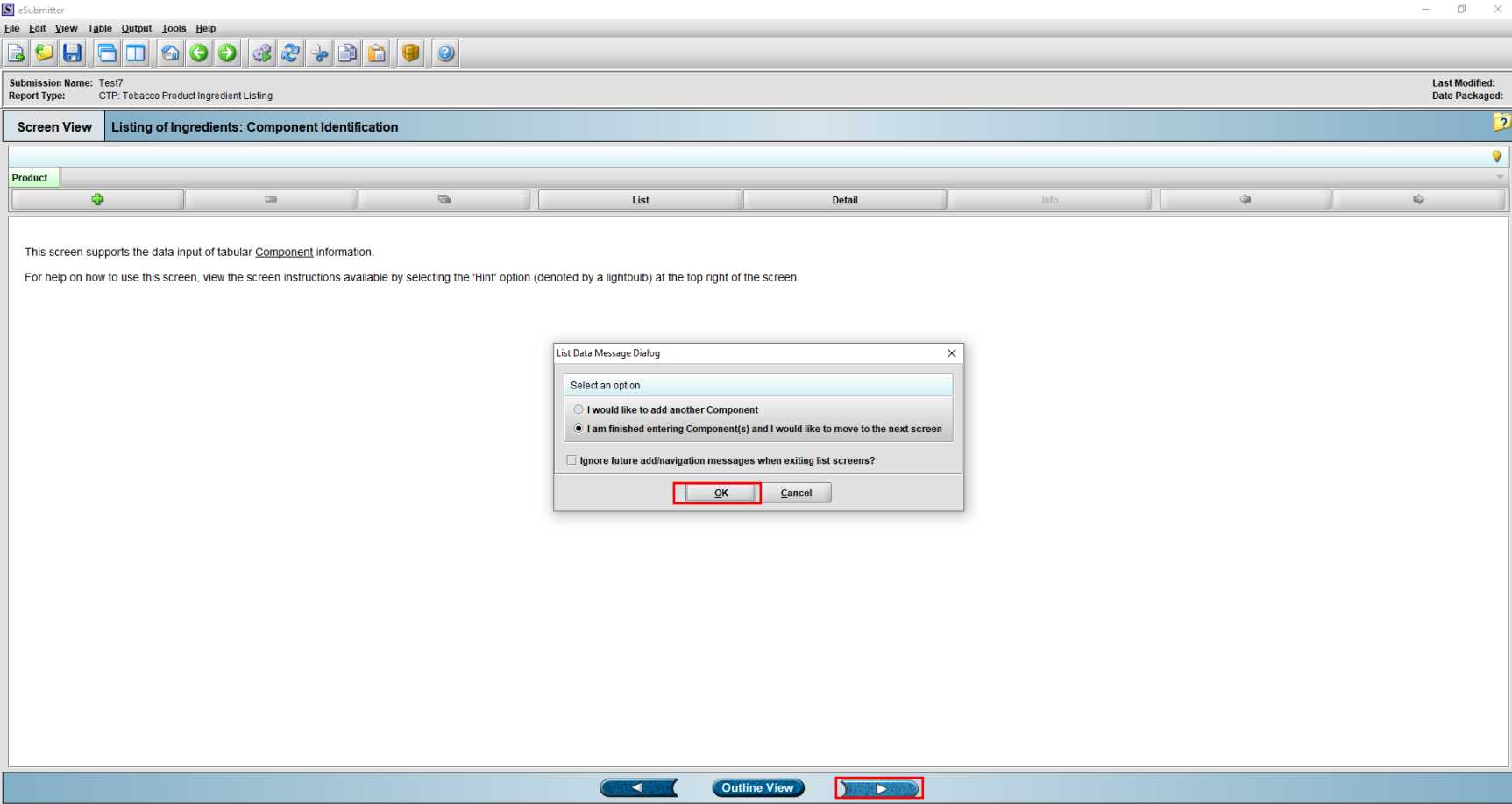
You will be prompted later to record any product(s) that you manufacture that are identical to the product above other than packaging differences that do not affect the characteristics of the product. You do not then need to submit separate ingredients listings for each of the products.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The status bar at the top shows 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. On the right side of the status bar, it says 'Last Modified: Date Packaged:'. The main window title is 'Listing of Ingredients: Ingredient Listing'. Below the title bar, there is a section for 'Ingredient Listing By Product' with a search bar and a 'Product' dropdown menu. A 'Component' dropdown menu is also visible. Below these are buttons for 'List', 'Detail', and 'Info'. The main content area contains the following text:

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

At the bottom of the window, there are navigation buttons: 'Previous Step', 'Outline View', and 'Next Step'. The 'Next Step' button is highlighted with a red box.

eSubmitter v3 CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The status bar at the top right shows "Last Modified:" and "Date Packaged:". The main window title is "Listing of Ingredients: Ingredient Listing". Below the title bar, there are tabs for "Product" and "Component". The main content area contains instructions on how to enter ingredient information, including a "Data Entry Method" section with four numbered steps and an "Import Method" section with five numbered steps. A "List Data Message Dialog" box is overlaid on the instructions, with the "OK" button highlighted by a red rectangle. The dialog box has a title bar "List Data Message Dialog" and a close button. It contains a "Select an option" label, two radio button options: "I would like to add another Ingredient" and "I am finished entering Ingredient(s) and I would like to move to the next screen", and a checkbox option "Ignore future add/navigation messages when exiting list screens?". At the bottom of the dialog are "OK" and "Cancel" buttons, with the "OK" button highlighted by a red rectangle. The bottom of the main window features a navigation bar with "Previous" and "Next" buttons, and an "Outline View" button.

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to add the ingredient to the list.
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 add the ingredient information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet icon.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the spreadsheet.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and exporting data.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the spreadsheet.
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.

List Data Message Dialog

Select an option

I would like to add another Ingredient

I am finished entering Ingredient(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

OK Cancel

eSubmitter v3

CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to enter information on 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

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
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 of the spreadsheet.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Table of Tobacco Products

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, If Other	Product Use	Co-Package?	Product Category
	1									
>	2									

2 of 9999 items in the list

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application interface. At the top, the title bar reads 'eSubmitter'. Below it is a menu bar with 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. A toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. A 'Screen View' tab is active, showing 'Listing of Ingredients: Product Listing'. Below this is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is displayed with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. The table contains two rows, with the second row selected. A 'List Data Message Dialog' box is open in the center, containing the following text: 'Select an option', 'I would like to add another Product', 'I am finished entering Product(s) and I would like to move to the next screen', and 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the application, there is a navigation bar with 'Outline View' and a right-pointing arrow button, which is also highlighted with a red box. The status bar at the bottom indicates '2 of 9999 items in the list'.

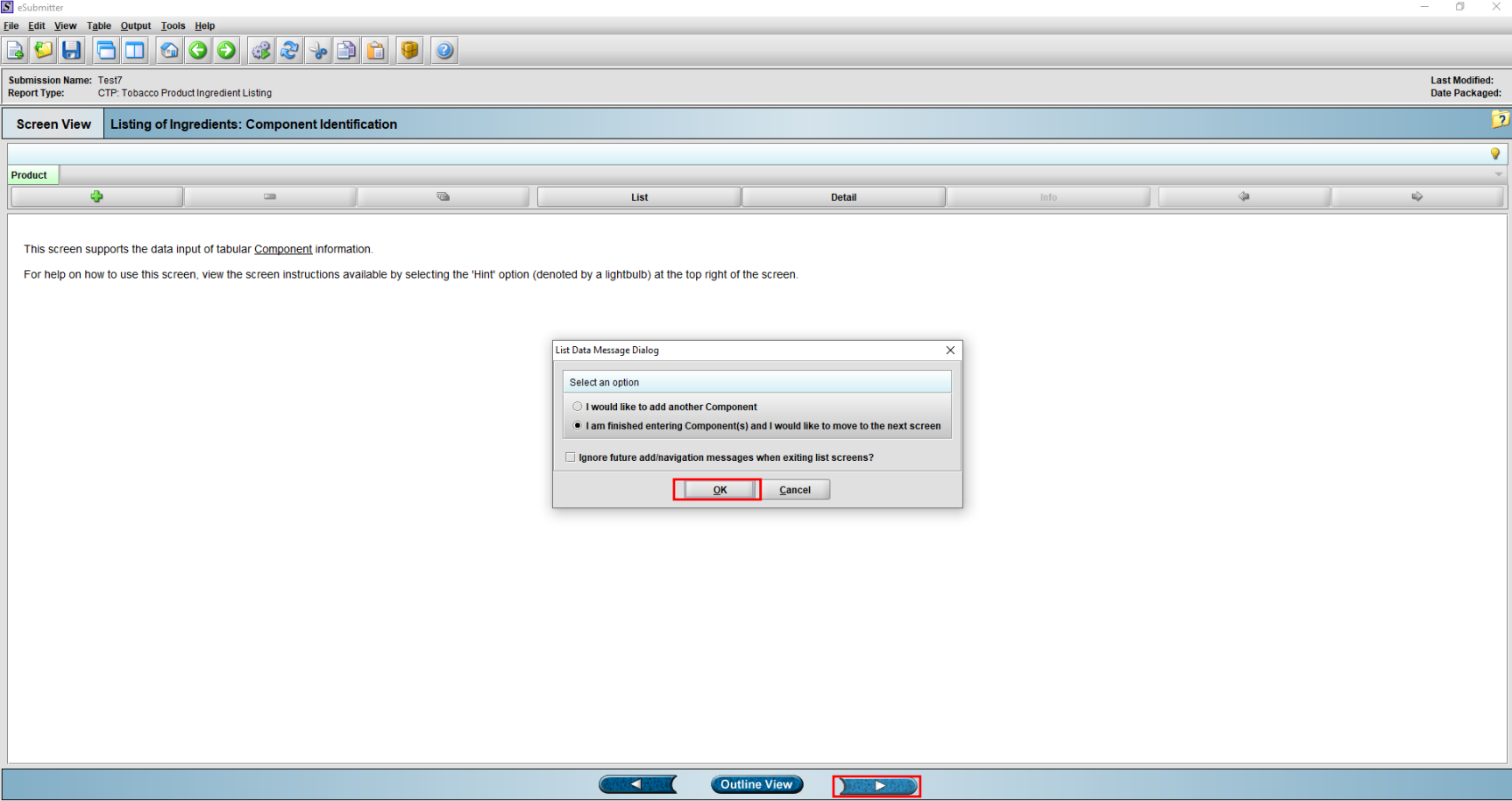
eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The status bar at the top shows 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. On the right side of the status bar, there are fields for 'Last Modified:' and 'Date Packaged:'. The main content area is titled 'Screen View Listing of Ingredients: Component Identification'. Below this title is a 'Product' tab and a navigation bar with buttons for '+', '-', 'List', 'Detail', 'Info', and arrows. The main area contains the following text:

This screen supports the data input of tabular [Component](#) information.
For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow button is highlighted with a red rectangle.

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3

CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

Previous Step Outline View Next Step

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The status bar at the top shows 'Submission Name: Test17' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The main window title is 'Listing of Ingredients: Ingredient Listing'. Below this, there are tabs for 'Product' and 'Component'. A navigation bar at the bottom of the main content area contains buttons for 'List', 'Detail', and 'Info'. The 'Info' button is highlighted with a red box. A dialog box titled 'List Data Message Dialog' is open, with the following text: 'Select an option', 'I would like to add another Ingredient', 'I am finished entering Ingredient(s) and I would like to move to the next screen', and 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button in the dialog is also highlighted with a red box. The main content area contains instructions on how to enter ingredient information, including sections for 'Data Entry Method' and 'Import Method'. The 'Data Entry Method' section includes a numbered list of steps. The 'Import Method' section includes a numbered list of steps. The 'Info' button in the bottom navigation bar is highlighted with a red box.

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the **"Add"** button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the **"Add"** button to enter information on 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 add the ingredient information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation information.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right of the spreadsheet.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Additional Information

If you used a spreadsheet to import product and ingredient data, you may attach it to the Additional Submission Documents attachment question.

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., Import Spreadsheet template for Product Identification, 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: 3/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". Below the menu bar is a toolbar with various icons for file operations and navigation. The main content area is titled "Confirmation: Instructions" and contains the following text:

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red rectangle. In the bottom right corner of the application area, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Confirmation: 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.

Identify the person submitting this form:

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar below the menu bar contains icons for file operations (New, Open, Save, Print, Copy, Paste, Undo, Redo, Home, Back, Forward, Stop, Refresh, Help) and a "Package" icon. The main content area is titled "Confirmation: Package Files for Submission" and contains the following text:

STOP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

At the bottom of the window, there is a navigation bar with a "Previous" button, an "Outline View" button, and a "Next" button. The "Next" button is highlighted with a red rectangle. In the bottom right corner, the text "OMB No. 0910-0650, Expiration Date: 3/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main window displays the following information:

- Submission Name:** Test7
- Report Type:** CTP: Tobacco Product Ingredient Listing
- Last Modified:** (blank)
- Date Packaged:** (blank)

The main content area is titled "Confirmation: Package Files for Submission" and contains the following text:

STOP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

A "Warning" dialog box is displayed in the center of the screen with the following text:

Warning

You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses.

The dialog box has a "Close" button.

At the bottom of the application window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow button is highlighted with a red box. In the bottom right corner of the application window, the text "OMB No. 0910-0630, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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. 0910-0630, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. At the top, the title bar reads 'eSubmitter'. Below it is a menu bar with 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. A toolbar contains various icons for file operations and navigation. The header area shows 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. On the right, there are fields for 'Last Modified:' and 'Date Packaged:'. A tab bar at the top of the main content area is labeled 'Listing of Ingredients: Role of Submitter'. The main content area features a section titled 'Statutory Requirements' with the following text:

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](#).

Below this text is a light blue box with the prompt 'Please identify your role:'. To the right of this box are two radio buttons: 'Manufacturer' (which is selected) and 'Importer'. At the bottom of the window, there is a navigation bar with a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow is highlighted with a red rectangle. In the bottom right corner of the window, the text 'OMB No. 0910-0650, Expiration Date: 5/21/2010' is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar below the menu bar contains various icons for file operations and navigation. The main content area is titled "Listing of Ingredients: Identification Information" and contains the following text:

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner of the window, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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):

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:

Generational Suffix:

Generational Suffix, if Other:

Professional Suffix (e.g., MD, Ph.D.):

Position Title:

Email Address:

Telephone Number(s):

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: U.S. Agent

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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):

Telephone Number(s) 0 of 4 items in the list

Fax Number:

Fax Number(s) 0 of 1 items in the list

Mailing Address for U.S. Agent

Company Name:

Country:

Address - Line 1:

Address - Line 2:

City:

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View | Listing of Ingredients: 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: You can import Product and Ingredient information by populating data onto the import Excel spreadsheet templates. The import spreadsheet templates can be found under the Info button on the respective Product and Ingredient screens. They can be accessed by clicking the "Import Spreadsheet Template" link under the Import Method section.

How will you provide Product, Component, Ingredient, and Identical Product Information?

- a) Enter product, component, and ingredient information manually on the following screens
- b) Enter product and ingredient information using separate CTP-provided spreadsheets, and enter component information manually
- c) Attach product, component, and ingredient information using a single CTP-provided spreadsheet
- d) Attach your own spreadsheet

Further instructions will appear in this section upon selection of a response to the above question.

Import Method for E-Liquid Products:
Click on the link ([Listing of Ingredients in Tobacco E-Liquid Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Leaf-Wrapped Cigar Products:
Click on the link ([Listing of Ingredients in Tobacco Leaf-Wrapped Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Ingredients in any Tobacco Product:
Click on the link ([Listing of Ingredients in Any Tobacco Product](#)) to launch the pre-formatted Excel spreadsheet.

Attach the Product, Component, Ingredient spreadsheet.

Title	Name	Date	Size	Path
-------	------	------	------	------

0 Items in the list

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The status bar at the top right shows 'Submission Name: Test7', 'Report Type: CTP: Tobacco Product Ingredient Listing', and 'Last Modified: Date Packaged:'. The main content area is titled 'Listing of Ingredients: Product Listing' and features a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. Below this is a 'Table of Tobacco Products' with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. The table contains two rows, with the second row selected. A scrollbar at the bottom indicates '2 of 9999 items in the list'. At the bottom of the window, there are navigation buttons: a left arrow, 'Outline View', and a right arrow (highlighted with a red box).

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. Below this, a 'Screen View' tab is active, showing 'Listing of Ingredients: Product Listing'. A 'Product Listing' section has buttons for 'List', 'Detail', and 'Info'. A 'Table of Tobacco Products' is visible with columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. A 'List Data Message Dialog' is open in the center, asking the user to 'Select an option' with two radio buttons: 'I would like to add another Product' and 'I am finished entering Product(s) and I would like to move to the next screen'. The second option is selected. There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. 'OK' and 'Cancel' buttons are at the bottom of the dialog. At the bottom of the application window, a status bar shows '2 of 9999 items in the list' and navigation buttons, including 'Outline View' and a right-pointing arrow button highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The 'Screen View' is 'Listing of Ingredients: Product Listing'. A 'Product Listing' toolbar is visible above a table titled 'Table of Tobacco Products'. The table has columns for Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, if Other, Product Use, Co-Package?, and Product Category. A dialog box titled 'List Data Message Dialog' is open, asking the user to select an option: 'I would like to add another Product' (selected) or 'I am finished entering Product(s) and I would like to move to the next screen'. There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the application, a status bar shows '2 of 9999 items in the list' and navigation buttons, with the 'Next' button also highlighted with a red box.

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, if Other	Product Use	Co-Package?	Product Category
	1									
▶	2									

List Data Message Dialog

Select an option

I would like to add another Product

I am finished entering Product(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

OK Cancel

2 of 9999 items in the list

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 3

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#####):

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?

Product Category:

> If Other, please describe further:

Product Sub-Category:

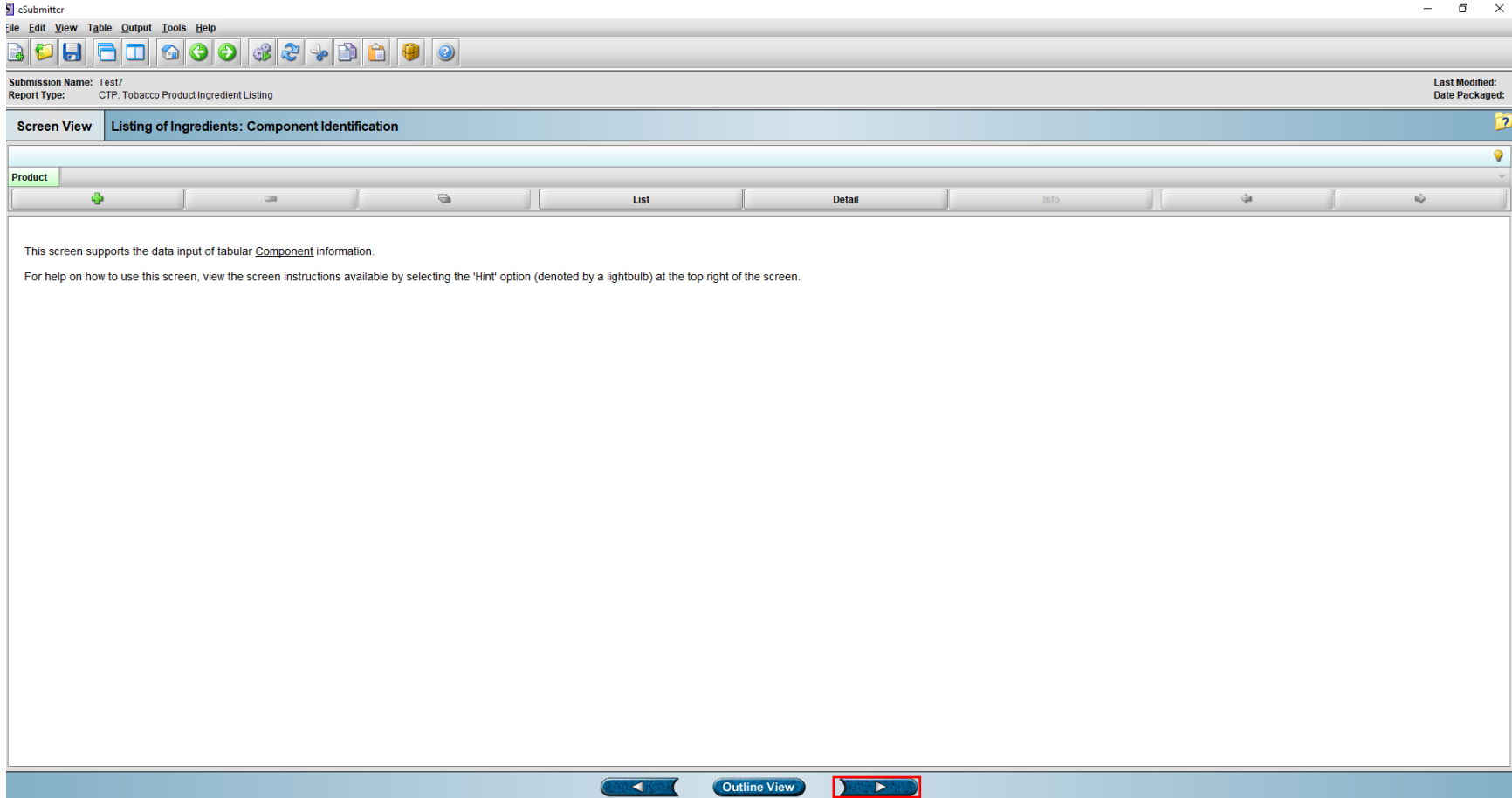
> If Other, please describe further:

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The main window content shows a "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". The current screen is titled "Listing of Ingredients: Component Identification". A "Product" tab is active, and navigation buttons for "List", "Detail", and "Info" are visible. A "List Data Message Dialog" is open in the center, prompting the user to "Select an option". The dialog contains two radio buttons: "I would like to add another Component" (unselected) and "I am finished entering Component(s) and I would like to move to the next screen" (selected). There is also a checkbox for "Ignore future add/navigation messages when exiting list screens?". The "OK" button is highlighted with a red box. At the bottom of the application window, a blue bar contains navigation arrows and an "Outline View" button, which is also highlighted with a red box.

eSubmitter v3

CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the **"Add"** button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 **"List"** to view and verify the imported product(s) information.

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

Outline View

eSubmitter v3 CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The status bar shows 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The main window title is 'Listing of Ingredients: Ingredient Listing'. Below the title bar, there are tabs for 'Product' and 'Component'. A toolbar contains buttons for 'List', 'Detail', and 'Info'. The main content area contains instructions on how to enter ingredient information, including sections for 'Data Entry Method' and 'Import Method'. A 'List Data Message Dialog' is open, with the following text: 'Select an option', 'I would like to add another Ingredient', 'I am finished entering Ingredient(s) and I would like to move to the next screen', and 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the window, there are navigation buttons for 'Outline View' and a red box around a right-pointing arrow button.

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View | Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to enter information.
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

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation information.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

the List and advance to this screen to add the Ingredient information.

[Click here for Ingredient Identification Updates](#) to launch the pre-formatted Excel spreadsheet. of the file during the import process.

and follow the import wizard.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Additional Information

If you used a spreadsheet to import product and ingredient data, you may attach it to the Additional Submission Documents attachment question.

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., Import Spreadsheet template for Product Identification, chart, graph, index, table of contents, etc.).

0 items in the list

Title	Name	Date	Size	Path
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Submission Comments
Please enter any submission comments below.

OMB No. 0910-0630, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area shows the "Confirmation: Instructions" screen. The breadcrumb navigation is "Introduction > Submitter Identification > Ingredient Listing > Confirmation". The text in the main area states: "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." The bottom navigation bar includes a left arrow, an "Outline View" button, and a right arrow button which is highlighted with a red rectangle. The footer text reads "OMB No. 0910-0650, Expiration Date: 5/31/2010".

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Confirmation: 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.

Identify the person submitting this form:

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area is titled "Confirmation: Package Files for Submission" and contains the following text:

STEP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red rectangle. In the bottom right corner of the window, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains icons for file operations and navigation. The main window area shows a "Confirmation: Package Files for Submission" screen. The submission details are: "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". A "Last Modified: Date Packaged:" field is also present. The confirmation text includes instructions on how to save, package, and transmit the submission. A "Warning" dialog box is open in the center, stating: "You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses." The "Close" button in the dialog is highlighted with a red box. At the bottom of the application, there is a navigation bar with "Outline View" and a right-pointing arrow button, which is also highlighted with a red box. The footer text reads "OMB No. 0910-0650, Expiration Date: 5/31/2010".

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View Listing of Ingredients: 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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View | Listing of Ingredients: 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](#).

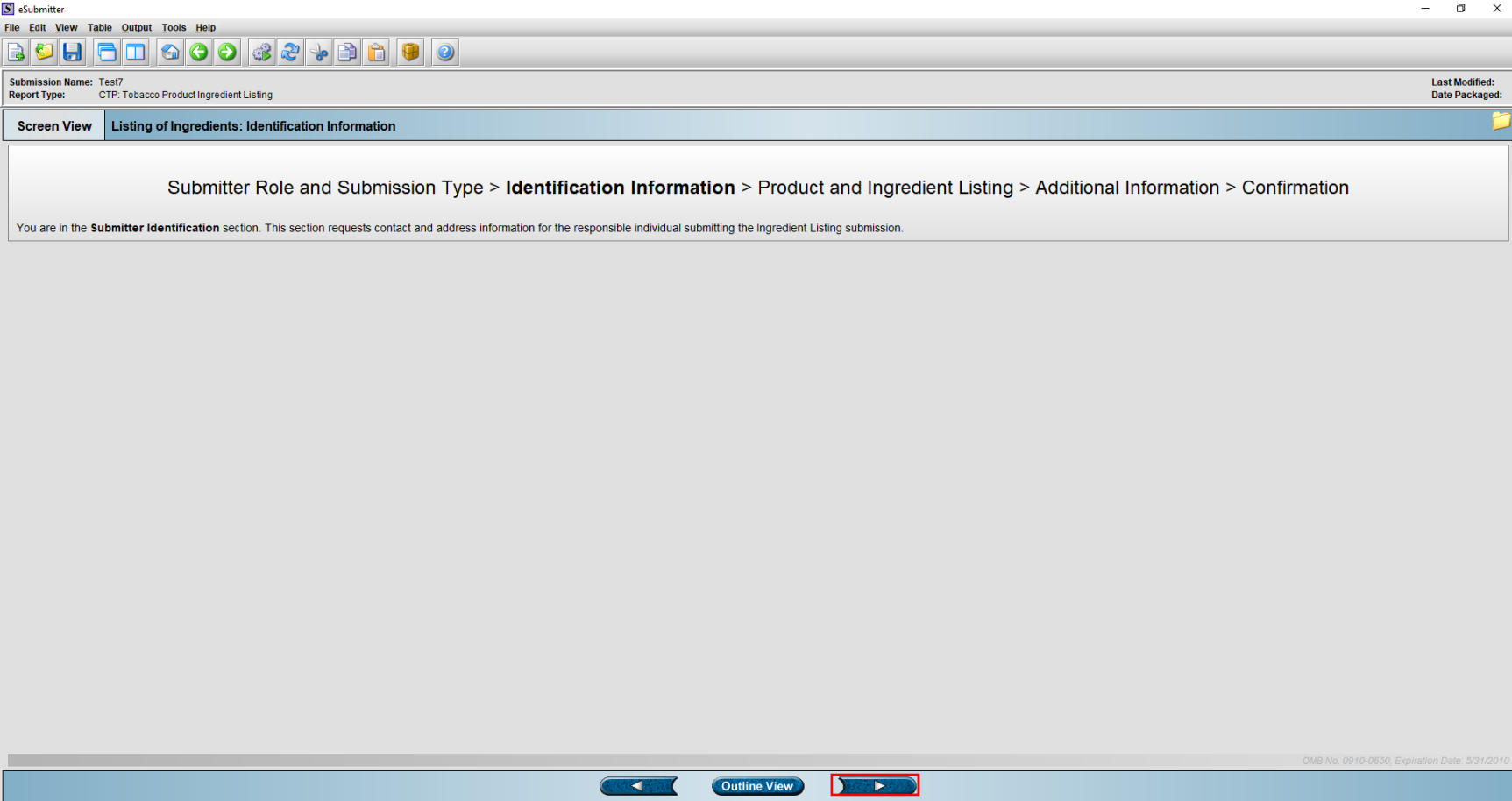
Please identify your role:

Manufacturer
 Importer

OMB No. 0910-0650, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main content area is titled 'Listing of Ingredients: Submitter Identification'. At the top right of this area, it says 'Last Modified: Date Packaged:'. Below this, there is a section for 'Company Information' with fields for Company Name, Company Headquarters D&B D-U-N-S® Number, Company Headquarters FDA Assigned Facility Establishment Identification (FEI) Number, and Organization URL. The next section is 'Company Mailing Address' with fields for Country, Address - Line 1, Address - Line 2, City, State, State, Province, or Territory Name, and Zip or Postal Code. The final section is 'Authorized Representative (Responsible official authorized to represent the submitter)' with fields for Prefix, First Name/Given Name, Middle Name, Last Name, Generational Suffix, Professional Suffix (e.g., MD, Ph.D.), Position Title, Email Address, and Telephone Number(s). At the bottom of the window, there are navigation buttons: a left arrow, 'Outline View', and a right arrow. The right arrow button is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: U.S. Agent

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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

Fax Number:

0 of 1 items in the list

Mailing Address for U.S. Agent

Company Name:

Country:

Address - Line 1:

Address - Line 2:

City:

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View | Listing of Ingredients: 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: You can import Product and Ingredient information by populating data onto the import Excel spreadsheet templates. The import spreadsheet templates can be found under the Info button on the respective Product and Ingredient screens. They can be accessed by clicking the "Import Spreadsheet Template" link under the Import Method section.

How will you provide Product, Component, Ingredient, and Identical Product Information?

- a) Enter product, component, and ingredient information manually on the following screens
- b) Enter product and ingredient information using separate CTP-provided spreadsheets, and enter component information manually
- c) Attach product, component, and ingredient information using a single CTP-provided spreadsheet
- d) Attach your own spreadsheet

Further instructions will appear in this section upon selection of a response to the above question.

Import Method for E-Liquid Products:
Click on the link ([Listing of Ingredients in Tobacco E-Liquid Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Leaf-Wrapped Cigar Products:
Click on the link ([Listing of Ingredients in Tobacco Leaf-Wrapped Products](#)) to launch the pre-formatted Excel spreadsheet.

Import Method for Ingredients in any Tobacco Product:
Click on the link ([Listing of Ingredients in Any Tobacco Product](#)) to launch the pre-formatted Excel spreadsheet.

Attach the Product, Component, Ingredient spreadsheet.

Title	Name	Date	Size	Path
-------	------	------	------	------

0 items in the list

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Table of Tobacco Products

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, If Other	Product Use	Co-Package?	Product Category
	1									
	2									
>	3									

3 of 9999 Items in the list

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The 'Screen View' is set to 'Listing of Ingredients: Product Listing'. Below this, there is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is displayed with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, if Other, Product Use, Co-Package?, and Product Category. The table has three rows, with the first row highlighted in yellow and the second in blue. A 'List Data Message Dialog' box is open in the center, containing the text 'Select an option', two radio button options: 'I would like to add another Product' (selected) and 'I am finished entering Product(s) and I would like to move to the next screen', and a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the application, there is a status bar showing '3 of 9999 items in the list' and a navigation bar with 'Outline View' and a right arrow button, which is also highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 4

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#####):

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?

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. A status bar at the top right shows 'Last Modified:' and 'Date Packaged:'. The current screen is 'Listing of Ingredients: Product Listing'. Below this is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is displayed with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. The table has 4 rows, with the first row highlighted in blue. A 'List Data Message Dialog' box is open in the center, containing the text 'Select an option', two radio buttons, and a checkbox. The 'OK' button is highlighted with a red box. At the bottom of the application, there is a navigation bar with 'Previous', 'Outline View', and 'Next' buttons, with the 'Next' button also highlighted with a red box. A status bar at the bottom indicates '4 of 9999 items in the list'.

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Table of Tobacco Products

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, If Other	Product Use	Co-Package?	Product Category
	1									
	2									
	3									
▶	4									

List Data Message Dialog

Select an option

I would like to add another Product

I am finished entering Product(s) and I would like to move to the next screen

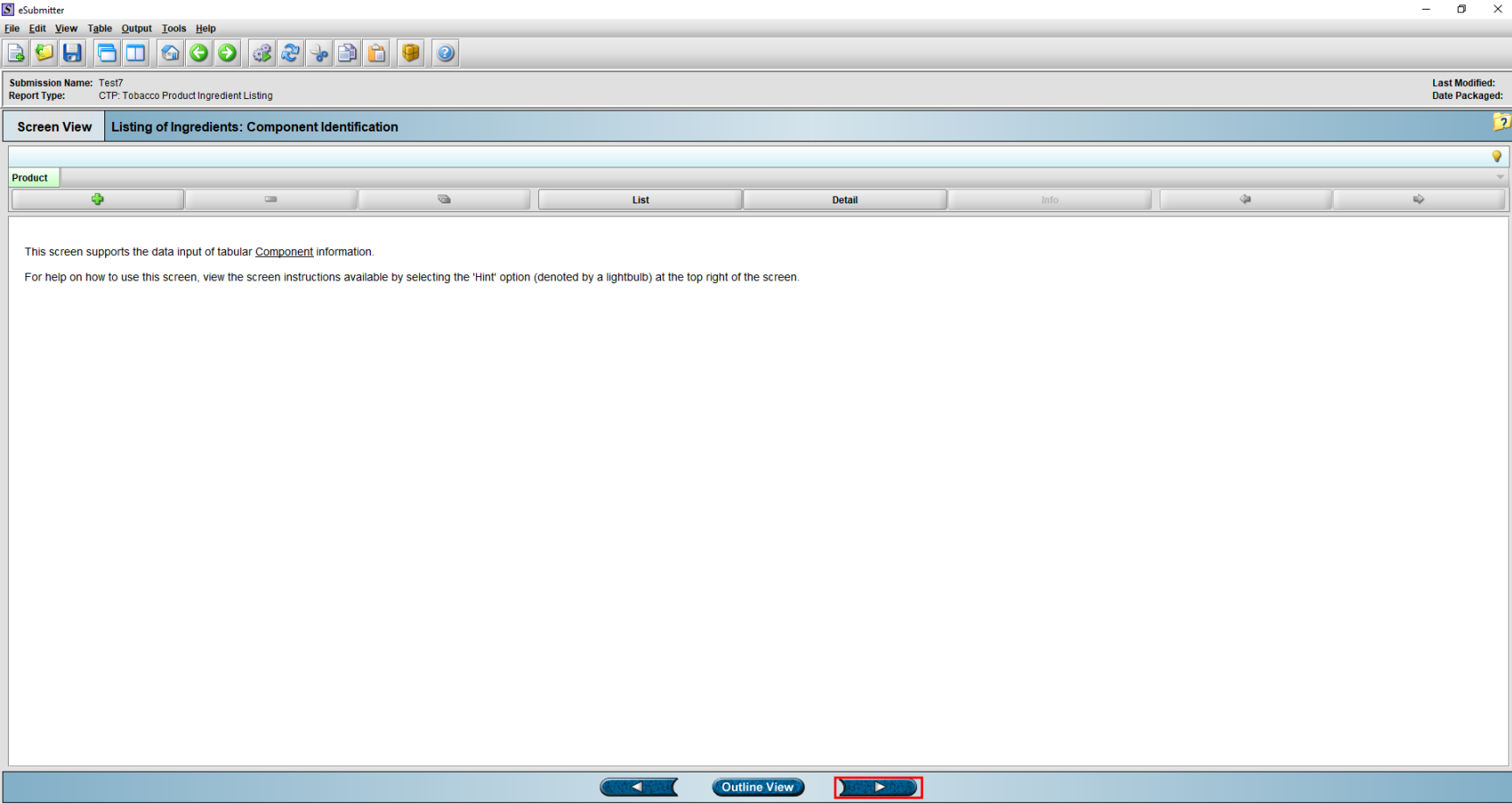
Ignore future add/navigation messages when exiting list screens?

OK Cancel

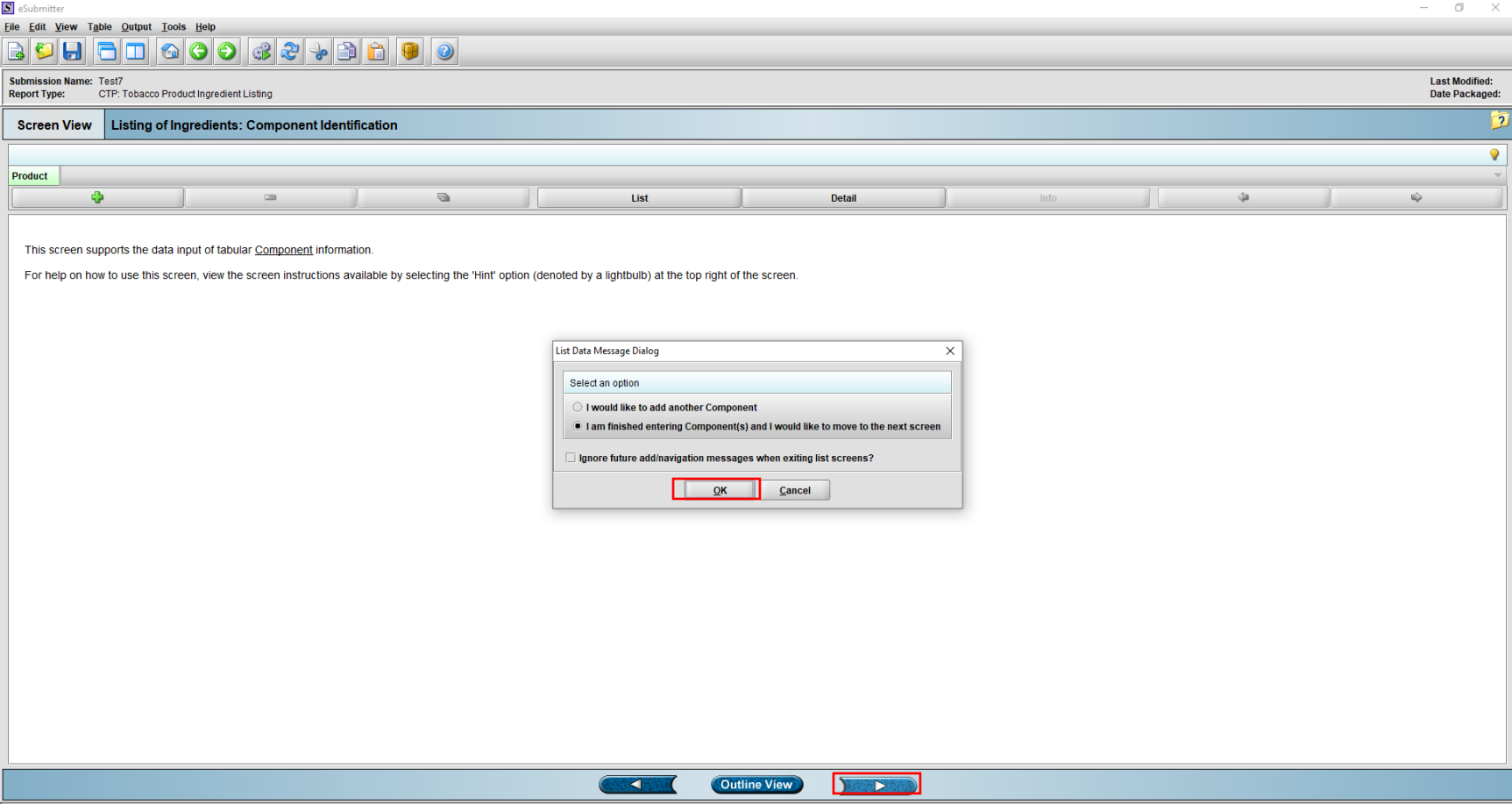
4 of 9999 items in the list

Previous Outline View Next

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3

CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the **"Add"** button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 **"List"** to view and verify the imported product(s) information.

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

Outline View

eSubmitter v3 CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main window area shows the "Listing of Ingredients: Ingredient Listing" screen. At the top, it displays "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". Below this, there are tabs for "Screen View" and "Listing of Ingredients: Ingredient Listing". The main content area is titled "Ingredient Listing By Product" and contains a table with columns for "Product" and "Component". Below the table, there are buttons for "List", "Detail", and "Info". The "Info" button is highlighted with a red box. The main content area also contains instructions on how to enter ingredient information, including a "Data Entry Method" and an "Import Method". A "List Data Message Dialog" is open in the foreground, asking the user to select an option: "I would like to add another Ingredient" (unselected) or "I am finished entering Ingredient(s) and I would like to move to the next screen" (selected). There is also a checkbox for "Ignore future add/navigation messages when exiting list screens?". The dialog has "OK" and "Cancel" buttons, with the "OK" button highlighted by a red box. At the bottom of the application window, there are navigation buttons for "Previous", "Outline View", and "Next", with the "Next" button highlighted by a red box.

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

List Data Message Dialog

Select an option

I would like to add another Ingredient

I am finished entering Ingredient(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

OK Cancel

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to enter information on 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 select a product and click the "List" button to view and verify the imported product information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
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 the spreadsheet.
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.

Screen Navigation Dialog

Select an option

I would like to add/select a new Product

I would like to add/select a new Component

Continue to the Next screen

OK Cancel

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Additional Information

If you used a spreadsheet to import product and ingredient data, you may attach it to the Additional Submission Documents attachment question.

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., Import Spreadsheet template for Product Identification, 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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". Below the menu bar is a toolbar with various icons. The main content area has a header with "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing" on the left, and "Last Modified:" and "Date Packaged:" on the right. A navigation bar below the header shows "Screen View" and "Confirmation: Instructions". The main content area displays a breadcrumb trail: "Introduction > Submitter Identification > Ingredient Listing > **Confirmation**". Below the breadcrumb, a text box contains the following information: "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." At the bottom of the window, there is a footer with "CMS No: 0910-0650, Expiration Date: 5/31/2010" and a navigation bar with buttons for "Previous", "Outline View", and "Next". The "Next" button is highlighted with a red rectangle.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area is titled "Confirmation: Confirmation Statement" and includes a warning message: "Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001." Below this is a text area with a 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." The form then prompts the user to "Identify the person submitting this form." and provides a dropdown menu. Below this is a section for "Contact Information" with fields for Prefix, First Name, Middle Name, Last Name, Generational Suffix, Generational Suffix, if Other, Professional Suffix, Position Title, and Email Address. There are also sections for "Telephone Number(s)" (0 of 4 items in the list) and "Fax Number(s)" (0 of 1 items in the list). At the bottom, there is a "Mailing Address" section and a navigation bar with "Outline View" and a right-pointing arrow button highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations. The main content area is titled "Confirmation: Package Files for Submission" and contains the following text:

STEP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main window area shows a "Confirmation: Package Files for Submission" screen. A red "STOP" icon is visible in the top left of the main content area. The text in the main content area provides instructions on how to package and submit the submission, including options for saving and re-opening the submission, and a warning about missing data. A "Warning" dialog box is open in the center of the screen, with a yellow warning icon and the text: "You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses." The "Close" button in the dialog box is highlighted with a red rectangle. At the bottom of the application window, there is a navigation bar with a "Next" button (a right-pointing arrow) highlighted with a red rectangle, and an "Outline View" button. The footer of the application window contains the text "OMB No. 0910-0650, Expiration Date: 5/31/2010".

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main content area is titled 'Submission Type' and contains the following text:

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.

At the bottom of the window, there are navigation buttons: a left arrow, 'Outline View', and a right arrow. The right arrow button is highlighted with a red rectangle. The footer text reads 'OMB No. 0910-0650, Expiration Date: 5/31/2010'.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main content area is titled 'Listing of Ingredients: Role of Submitter' and contains the following text:

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

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner, the text 'OMB No. 0910-0650, Expiration Date: 5/31/2010' is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar features icons for file operations and navigation. The main content area shows the "Listing of Ingredients: Identification Information" section, which includes a breadcrumb trail: "Submitter Role and Submission Type > Identification Information > Product and Ingredient Listing > Additional Information > Confirmation". Below the breadcrumb, a message states: "You are in the **Submitter Identification** section. This section requests contact and address information for the responsible individual submitting the Ingredient Listing submission." The bottom of the window features a navigation bar with "Previous" and "Next" buttons, a central "Outline View" button, and a "Next" button highlighted with a red box. The footer contains the text "OMB No. 0910-0650, Expiration Date: 5/31/2010".

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar shows 'eSubmitter' and standard window controls. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains icons for file operations and navigation. The main content area is titled 'Listing of Ingredients: Submitter Identification' and contains the following sections:

- Company Information:** Fields for Company Name, Company Headquarters D&B D-U-N-S® Number, Company Headquarters FDA Assigned Facility Establishment Identification (FEI) Number, and Organization URL (e.g., www.fda.gov).
- Company Mailing Address:** Fields for Country (dropdown), Address - Line 1, Address - Line 2, City, State (dropdown), State, Province, or Territory Name, and Zip or Postal Code.
- Authorized Representative (Responsible official authorized to represent the submitter):** Fields for Prefix (dropdown), First Name/Given Name, Middle Name, Last Name, Generational Suffix (dropdown), Generational Suffix, if Other, Professional Suffix (e.g., MD, Ph.D.), Position Title, Email Address, and Telephone Number(s).

At the bottom of the form, there is a navigation bar with a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow button is highlighted with a red rectangular box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: U.S. Agent

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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):

Telephone Number(s) 0 of 4 items in the list

Fax Number:

Fax Number(s) 0 of 1 items in the list

Mailing Address for U.S. Agent

Company Name:

Country:

Address - Line 1:

Address - Line 2:

City:

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays the following information:

- Submission Name: Test7
- Report Type: CTP: Tobacco Product Ingredient Listing
- Last Modified: (blank)
- Date Packaged: (blank)

The 'Screen View' section is titled 'Listing of Ingredients: Product Listing'. Below this is a 'Product Listing' header with a search icon and a refresh icon. A toolbar contains buttons for 'List', 'Detail', and 'Info'. The main content area is a 'Table of Tobacco Products' with the following columns:

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, If Other	Product Use	Co-Package?	Product Category
	1									
	2									
	3									
▶	4									

At the bottom of the table, a status bar indicates '4 of 9999 items in the list'. Below the table is a navigation bar with a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow button is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. A status bar at the top right shows 'Last Modified:' and 'Date Packaged:'. The current screen is 'Listing of Ingredients: Product Listing'. Below this, there is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is displayed with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. The table has 4 rows, with the first row highlighted in blue. A 'List Data Message Dialog' box is open in the center, containing the text 'Select an option' and two radio button options: 'I would like to add another Product' (selected) and 'I am finished entering Product(s) and I would like to move to the next screen'. There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the application, there is a navigation bar with 'Outline View' and a right-pointing arrow button, also highlighted with a red box. A status bar at the bottom indicates '4 of 9999 items in the list'.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 5

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#####):

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?

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 5

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#####):

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?

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar below the menu bar contains various icons for file operations and navigation. The main content area is titled "Listing of Ingredients: Component Identification" and includes a "Product" dropdown menu. Below the dropdown is a navigation bar with buttons for "List", "Detail", and "Info". The main area contains instructional text: "This screen supports the data input of tabular Component information. For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen." At the bottom of the window, there is a navigation bar with a left arrow, an "Outline View" button, and a right arrow button which is highlighted with a red rectangle.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The status bar at the top shows "Submission Name: Test7" and "Report Type: CTP Tobacco Product Ingredient Listing". The main window title is "Screen View Listing of Ingredients: Component Identification". Below the title bar, there is a "Product" dropdown menu and a navigation bar with buttons for "List", "Detail", and "Info". The main content area contains the following text:

This screen supports the data input of tabular Component information.
For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen.

A "List Data Message Dialog" box is open in the center of the screen. It contains the following options:

- Select an option
- I would like to add another Component
- I am finished entering Component(s) and I would like to move to the next screen
- Ignore future add/navigation messages when exiting list screens?

The "OK" button in the dialog box is highlighted with a red box. At the bottom of the application window, a navigation bar contains a "Next" button, which is also highlighted with a red box. The "Outline View" button is visible in the center of the navigation bar.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window area shows the following information:

- Submission Name:** Test17
- Report Type:** CTP: Tobacco Product Ingredient Listing
- Last Modified:** (blank)
- Date Packaged:** (blank)

The main content area is titled 'Screen View Listing of Ingredients: Ingredient Listing'. Below this, there is a section for 'Ingredient Listing By Product' with a 'Product' dropdown menu and a 'Component' dropdown menu. A navigation bar contains buttons for '+', '-', 'List', 'Detail', 'Info', and a yellow lightbulb icon.

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the **"Add"** button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 **"List"** to view and verify the imported product(s) information.

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

At the bottom of the window, there is a navigation bar with buttons for 'Outline View' and a right-pointing arrow button, which is highlighted with a red box.

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View | Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button.
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 advance to this screen to add the ingredient information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet icon.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the spreadsheet.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and saving the spreadsheet.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the spreadsheet.
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.

List Data Message Dialog

Select an option

I would like to add another Ingredient

I am finished entering Ingredient(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

OK Cancel

Outline View

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View | Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. This will allow you to select the appropriate spreadsheet for your submission type.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
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 of the spreadsheet.
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.

Screen Navigation Dialog

Select an option

- I would like to add/select a new Product
- I would like to add/select a new Component
- Continue to the Next screen

OK Cancel

Previous Outline View Next

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Additional Information

If you used a spreadsheet to import product and ingredient data, you may attach it to the Additional Submission Documents attachment question.

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., Import Spreadsheet template for Product Identification, chart, graph, index, table of contents, etc.).

Title	Name	Date	Size	Path
0 Items in the list				

Submission Comments

Please enter any submission comments below.

OMB No. 0910-0650, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area displays the following information:

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Confirmation: 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.

At the bottom of the window, there is a navigation bar with a left arrow, an "Outline View" button, and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test17
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Confirmation: 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.

Identify the person submitting this form:

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains icons for file operations (Save, Open, Print, Copy, Paste, Undo, Redo, Refresh, Home, Back, Forward, Stop, Help) and a "Package" icon. The main content area has a header with "Submission Name: Test7" and "Report Type: CTP: Tobacco Product Ingredient Listing". On the right, it shows "Last Modified:" and "Date Packaged:". Below this is a tabbed interface with "Screen View" selected and "Confirmation: Package Files for Submission" as the active tab. The main area contains a "STEP" icon and the following text:

You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

At the bottom right of the main area, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible. The footer bar contains navigation buttons: a left arrow, a button labeled "Outline View", and a right arrow (highlighted with a red box).

eSubmitter v3

CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains icons for file operations and navigation. The main window content shows:

- Submission Name:** Test7
- Report Type:** CTP: Tobacco Product Ingredient Listing
- Last Modified:**
- Date Packaged:**

The main area is titled "Confirmation: Package Files for Submission". It contains a "STOP" icon and the following text:

You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

A "Warning" dialog box is displayed in the center of the screen with the following text:

You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses.

The dialog box has a "Close" button. At the bottom of the application window, there is a navigation bar with a "Next" button (highlighted with a red box) and an "Outline View" button.

OMB No. 0919-0650, Expiration Date: 5/31/2010

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View | Listing of Ingredients: 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:

DMB No. 0910-0650, Expiration Date: 3/31/2010

Previous Step | Outline View | Next Step

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter" and includes standard window controls. The menu bar contains "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar below the menu bar contains various icons for file operations and navigation. The main content area is titled "Listing of Ingredients: Identification Information" and contains the following text:

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red rectangle. In the bottom right corner of the window, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: 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):

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:

Generational Suffix:

Generational Suffix, if Other:

Professional Suffix (e.g., MD, Ph.D.):

Position Title:

Email Address:

Telephone Number(s):

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View Listing of Ingredients: U.S. Agent

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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:

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays the following information:

- Submission Name: Test7
- Report Type: CTP: Tobacco Product Ingredient Listing
- Last Modified: (blank)
- Date Packaged: (blank)

The 'Screen View' tab is active, showing 'Listing of Ingredients: Product Listing'. Below this, there is a 'Product Listing' section with a toolbar containing a plus icon, a minus icon, a list icon, a detail icon, an info icon, and a refresh icon. The main area displays a 'Table of Tobacco Products' with the following columns:

>	Item	Product Name	FDA-Assigned Tracking Number	STN Application #	Unique Product ID	Type of Unique Product ID	Type of Unique Product ID, if Other	Product Use	Co-Package?	Product Category
	1									
	2									
	3									
	4									
>	5									

At the bottom of the window, there is a status bar that reads '5 of 9999 items in the list'. Below the status bar, there are navigation buttons: a left arrow, a button labeled 'Outline View', and a right arrow. The right arrow button is highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window displays 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. A 'Screen View' tab is active, showing 'Listing of Ingredients: Product Listing'. Below this is a 'Product Listing' section with a toolbar containing 'List', 'Detail', and 'Info' buttons. A 'Table of Tobacco Products' is displayed with the following columns: Item, Product Name, FDA-Assigned Tracking Number, STN Application #, Unique Product ID, Type of Unique Product ID, Type of Unique Product ID, If Other, Product Use, Co-Package?, and Product Category. The table has 5 rows, with the first row selected. A 'List Data Message Dialog' box is open in the center, asking the user to 'Select an option'. The options are: 'I would like to add another Product' (selected) and 'I am finished entering Product(s) and I would like to move to the next screen'. There is also a checkbox for 'Ignore future add/navigation messages when exiting list screens?'. The 'OK' button is highlighted with a red box. At the bottom of the window, there is a status bar showing '5 of 9999 items in the list' and a navigation bar with 'Outline View' and a right arrow button, which is also highlighted with a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View Listing of Ingredients: Product Listing

Product Listing

Item: 6

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#####):

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.

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View Listing of Ingredients: Product Listing

Item: 6

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#####):

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:

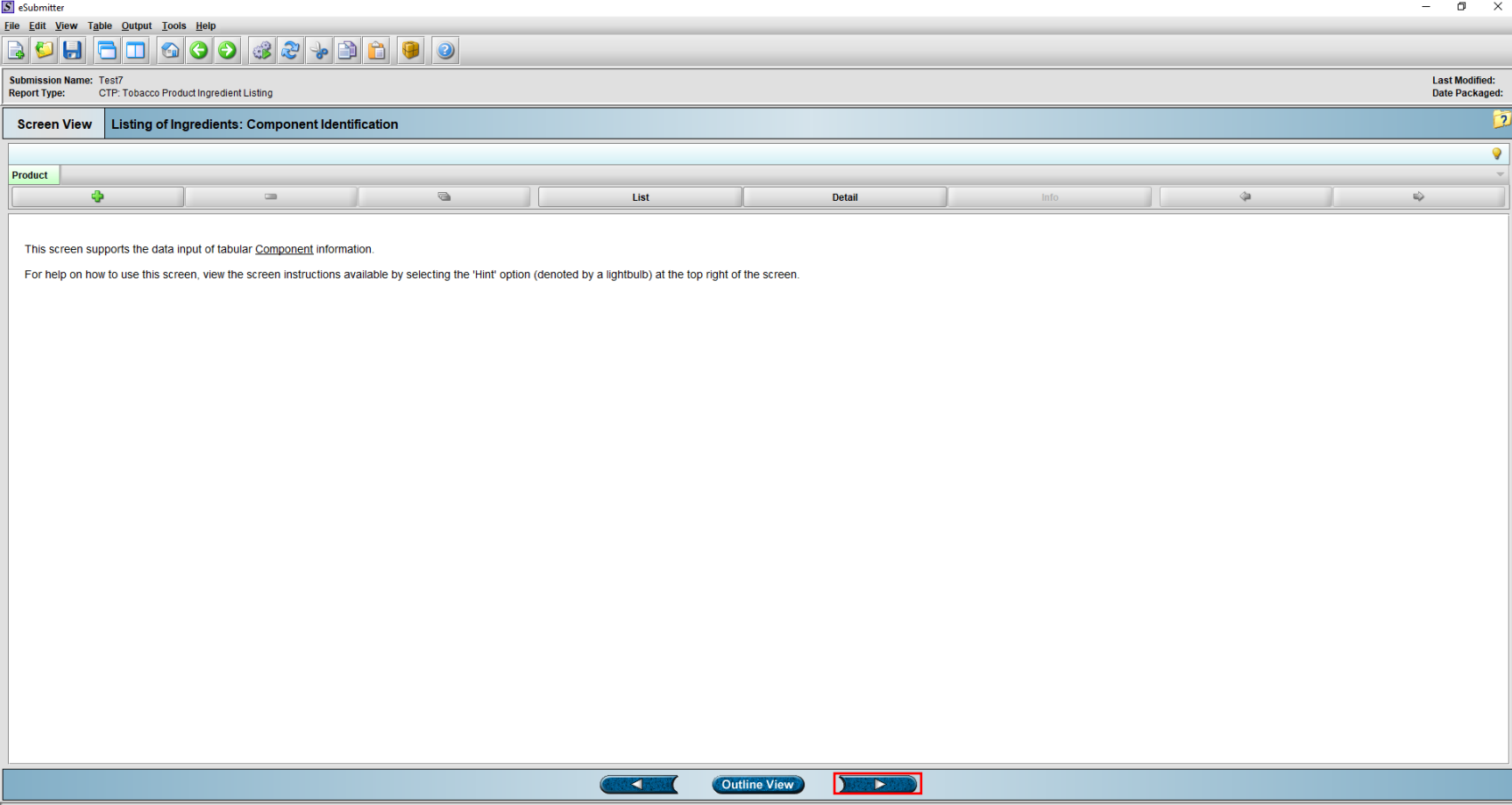
Product Sub-Category:

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.

Previous Outline View Next

eSubmitter v3
CTP Tobacco Product Manufacturer form



eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window header shows 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The current screen is titled 'Listing of Ingredients: Component Identification'. Below the header, there is a 'Product' tab and a navigation bar with buttons for 'List', 'Detail', and 'Info'. The main content area contains the following text:

This screen supports the data input of tabular Component information.
For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen.

A 'List Data Message Dialog' box is open in the center of the screen. It contains the following options:

- Select an option
- I would like to add another Component
- I am finished entering Component(s) and I would like to move to the next screen
- Ignore future add/navigation messages when exiting list screens?

The 'OK' button in the dialog is highlighted with a red box. At the bottom of the application window, there is a navigation bar with a left arrow, an 'Outline View' button, and a right arrow, with the right arrow also highlighted by a red box.

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window area shows the following information:

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Screen View: Listing of Ingredients: Ingredient Listing

Ingredient Listing By Product

Product
Component

Buttons: 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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on 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. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link. Then, click on the link ([Import Spreadsheet Template for Ingredient Identification Updates](#)) 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 "List" to view and verify the imported product(s) information.

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

Navigation buttons at the bottom: Previous, Outline View, Next (highlighted with a red box).

eSubmitter v3 CTP Tobacco Product Manufacturer form

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified:
Date Packaged:

Screen View | **Listing of Ingredients: Ingredient Listing**

Ingredient Listing By Product

Product
Component

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular ingredient, click on the "Add" button to add the ingredient to the list.
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 add the Ingredient information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet icon.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the spreadsheet.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and data entry.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the spreadsheet.
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.

List Data Message Dialog

Select an option

I would like to add another Ingredient

I am finished entering Ingredient(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

OK Cancel

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The toolbar contains various icons for file operations and navigation. The main window area shows the 'Listing of Ingredients: Ingredient Listing' screen. At the top right, it indicates 'Last Modified:' and 'Date Packaged:'. Below the title bar, there are fields for 'Submission Name: Test7' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The main content area is titled 'Ingredient Listing By Product' and contains instructions for entering ingredient information. A 'Screen Navigation Dialog' is overlaid on the screen, asking the user to select an option: 'I would like to add/select a new Product', 'I would like to add/select a new Component', or 'Continue to the Next screen'. The 'Continue to the Next screen' option is selected. At the bottom of the screen, there is a navigation bar with buttons for 'Outline View' and 'Next', which is highlighted with a red box.

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. *Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.*

Data Entry Method:

1. To begin, click on the "Add" button to enter information on a particular ingredient.
2. Once you have entered the information about a particular Ingredient, click on the "Add" button to enter information on 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 the product information.

Import Method:

1. You **MUST** select a Submission Type (the first question of this form) prior to clicking the spreadsheet link.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation process.
4. Once you have entered the information into the spreadsheet, click the Import Data button on the top right of the spreadsheet.
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.

the List and advance to this screen to add the Ingredient information.

[Click here for Ingredient Identification Updates](#) to launch the pre-formatted Excel spreadsheet of the file during the import process.

and follow the import wizard.

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Listing of Ingredients: Additional Information

If you used a spreadsheet to import product and ingredient data, you may attach it to the Additional Submission Documents attachment question.

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., Import Spreadsheet template for Product Identification, chart, graph, index, table of contents, etc.).

0 items in the list

Title	Name	Date	Size	Path
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Submission Comments
Please enter any submission comments below.

OMB No. 0910-0650, Expiration Date: 5/31/2010

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main content area displays the following information:

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View | Confirmation: 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. 0910-0630, Expiration Date: 3/31/2010

Navigation buttons: Previous, Outline View, Next (highlighted with a red box).

eSubmitter v3
CTP Tobacco Product Manufacturer form

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View Confirmation: 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.

Identify the person submitting this form:

To use the eSubmitter's Address book, use the appropriate copy icons to the right.

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

Outline View

eSubmitter v3
CTP Tobacco Product Manufacturer form

The screenshot shows the eSubmitter v3 application window. The title bar reads "eSubmitter" and the menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and submission. The main content area displays the following information:

Submission Name: Test7
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified:
Date Packaged:

Screen View | **Confirmation: Package Files for Submission**

STEP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

At the bottom of the window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow is highlighted with a red box. In the bottom right corner, the text "OMB No. 0910-0650, Expiration Date: 5/31/2010" is visible.

eSubmitter v3 CTP Tobacco Product Manufacturer form

The screenshot displays the eSubmitter v3 application window. The title bar reads "eSubmitter". The menu bar includes "File", "Edit", "View", "Table", "Output", "Tools", and "Help". The toolbar contains various icons for file operations and navigation. The main window area shows a "Screen View" tab with the title "Confirmation: Package Files for Submission". Below this, a pink-shaded instruction box contains the following text:

STOP You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.

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.

A "Warning" dialog box is centered on the screen, containing the following text:

Warning

You have reached the end of the Submission form. However, the report is incomplete due to missing data. Select the Missing Data Report from the Output menu to easily identify all missing responses.

Close

At the bottom of the application window, there is a navigation bar with a left arrow, a button labeled "Outline View", and a right arrow. The right arrow button is highlighted with a red rectangle. In the bottom right corner of the application window, the text "OMB No. 0910-0630, Expiration Date: 3/31/2010" is visible.