

MEMORANDUM

Via Electronic Mail

TO: E-Vapor Symposium Attendees

FROM: Azim Chowdhury (chowdhury@khlaw.com)
Benjamin Wolf
Keller and Heckman LLP

DATE: February 2, 2017

RE: **Step-by-Step Instructions for Submitting Ingredient Listing Reports to FDA**

This memorandum provides step-by-step instructions for submitting the ingredient listing reports required by the U.S. Food and Drug Administration (FDA) using FDA's eSubmitter tool and the Center for Tobacco Product (CTP) online portal. Please be advised that on December 28, 2016, FDA finalized its Guidance for Industry, "Listing of Ingredients in Tobacco Products" which effectively extended the deadline to submit ingredient listing reports by 6 months, to August 8, 2017 for non-small scale manufacturers, and until February 8, 2018 for small-scale manufacturers (a small-scale manufacturer must earn less than \$5 million in revenues annual and have fewer than 150 full-time employees). FDA believes that this additional time will allow manufacturers to prepare higher quality submissions, and encourages manufacturers to begin the process as early as possible. For more background information on the ingredient listing requirement, see: <https://www.khlaw.com/FDAs-Ingredient-Listing-Deadline-Rapidly-Approaching-for-Manufacturers-of-E-Vapor-E-Liquid-and-Other-Deemed-Tobacco-Products>.

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Using eSubmitter to Submit Ingredient Listing

There are 9 general steps required to submit an ingredient listing to CTP:

- 1) Establish a CTP Portal Account
- 2) Set up your CTP Portal Account
- 3) Download eSubmitter
- 4) Create a digital signature
- 5) Collect information to enter in eSubmitter
- 6) Set up eSubmitter
- 7) Enter product information into eSubmitter
- 8) Package your submission
- 9) Upload the submission to FDA using the CTP Portal

The CTP Portal is used to upload documents including, but not limited to, Ingredient Listings, Reporting of Harmful and Potentially Harmful Constituents (HPHCs), Health Documents, Apply to Market documents, and Product Applications. Background information on the CTP Portal can be found here:

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>

Establishing and setting up a CTP Portal Account is not hard or time consuming, but you will have to wait for FDA to take action so you should begin the process at least 3 weeks prior to needing to submit information.

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1. Establish a CTP Portal Account:

- 1) Verify that no one else in your organization currently has an account
- 2) Once you confirm that no one has an account, you then designate to FDA, in writing, an Industry Account Manager (IAM) for your organization.
 - a. The IAM is primarily responsible for creating and managing user accounts, however, they also are able to submit filings.
- 3) To request an IAM, email the CTP Portal Helpdesk at CTPeSub@fda.hhs.gov with subject line “IAM Request.”
- 4) A signed letter that designates the IAM, provides contact information, and certifies compliance with regards to electronic signatures should be attached to your request email.
- 5) Once you send this letter electronically, you will need to mail a hard copy to this address:

Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

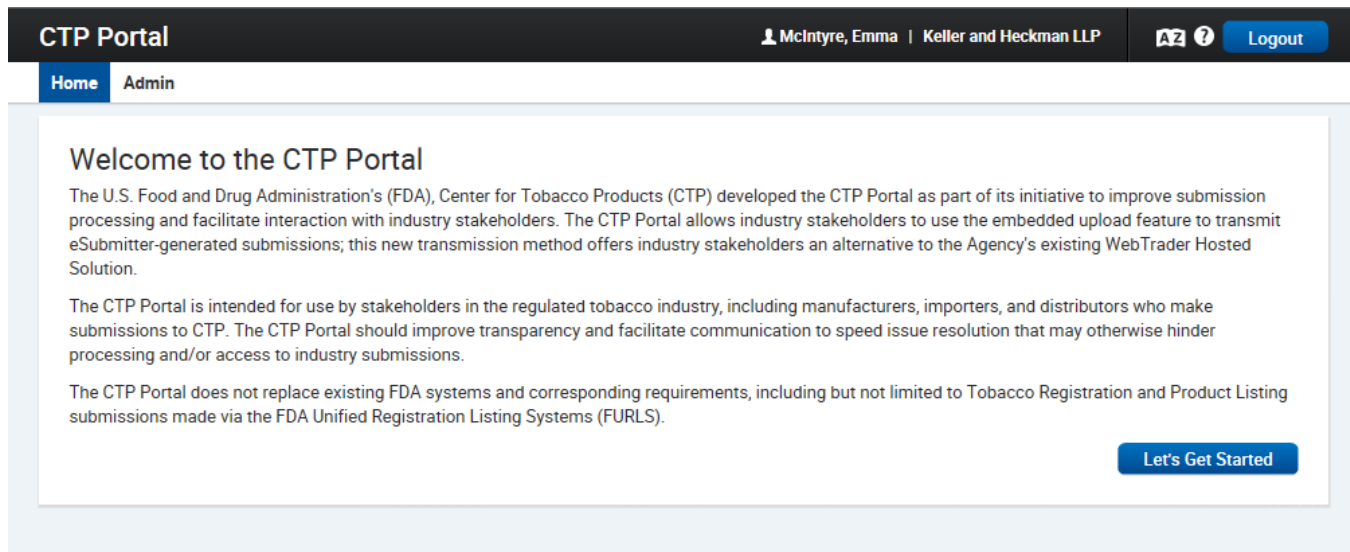
Information regarding IAMs along with instructions for executing the request letter can be found here:

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515185.htm>.

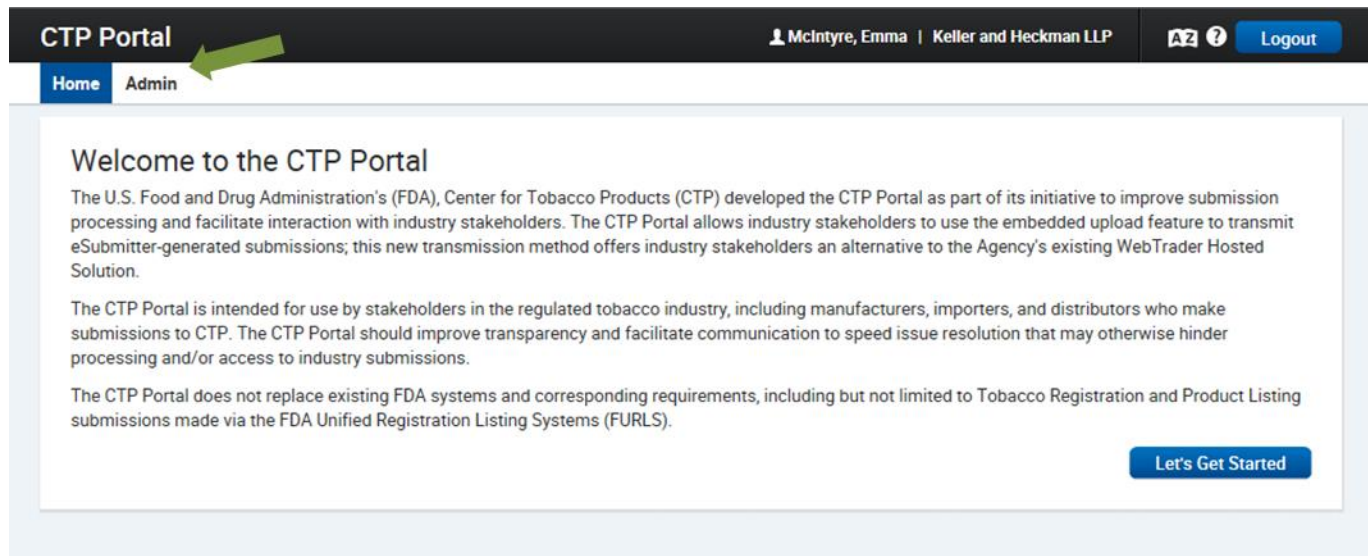
- 6) Once the hard copy has been received by CTP, the IAM will be contacted via email after their portal account has been created.
- 7) Once the IAM has activated his/her account, he/she can send invitations to additional members of the organization to create their accounts while managing each user’s account privileges.

2. Set up your CTP Portal Account

- 1) Below is a homepage that only has administrative access (indicating that this is the IAM):



- 2) To edit user privileges, click the “Admin” tab



- 3) Either click “Add New User” to create a new user within your organization, or click “Edit” to update a current user’s privileges

The screenshot shows the CTP Portal Admin interface. The top navigation bar includes 'Home' and 'Admin' tabs. The 'Admin' tab is active, and the 'Manage Users' sub-tab is selected. A green arrow points to the '+ Add New User' button. Below this is a table of users with columns: Last Name, First Name, Username, Email, Privilege, and User Status. The table lists four users: Chaput, Chowdhury, DiPano, and McIntyre. The McIntyre row is highlighted, and a green arrow points to the 'Edit' link in the 'User Status' column.

Last Name	First Name	Username	Email	Privilege	User Status
Chaput	Owen	owen.chaput@kah	chaput@khlaw.com	CTP Portal View/Reply Messages... (4)	Active View Edit
Chowdhury	Azim	azim.chowdhury@kah	chowdhury@khlaw.com	CTP Portal View/Reply Messages... (4)	Active View Edit
DiPano	Kristina	kristina.dipano@kah	dipano@khlaw.com	CTP Portal View/Reply Messages... (4)	Initiated View Edit
McIntyre	Emma	emma.mcintyre@kah	mcintyre@khlaw.com	CTP Portal User Admin	Active View Edit

- 4) If you create a new user, fill in the pertinent information fields and make sure to select ALL privileges, except “CTP Portal User Admin.” The IAM is most likely the only person who needs “CTP Portal User Admin” privileges

The screenshot displays the 'CTP Portal' Admin interface. At the top, the header includes the logo, user information (McIntyre, Emma | Keller and Heckman LLP), and a 'Logout' button. The main navigation bar shows 'Home' and 'Admin' tabs. Under the 'Admin' tab, there are two sub-tabs: 'Manage Users' and 'Manage Employers'. The 'Add New User' form is visible, containing several input fields for user details: Position Title, Email, Title (dropdown), First Name, Middle Name, Last Name, Generational Suffix (dropdown), and Professional Suffix. A red box highlights the 'Privileges' section, which shows a list of permissions with checkboxes. The permissions listed are: CTP Portal View Submission-Related Information, CTP Portal View/Reply Messages, CTP Portal View Only Messages, CTP Portal Upload, and CTP Portal User Admin. The 'CTP Portal User Admin' checkbox is unchecked. To the right of the privileges list, there is a section for 'Is the User a Direct Employee of: Keller and Heckman LLP' with radio buttons for 'Yes' and 'No, the user is an agent'. At the bottom right of the form are 'Cancel' and 'Save' buttons.

CTP Portal

McIntyre, Emma | Keller and Heckman LLP

Logout

Home Admin

Admin

Manage Users Manage Employers

Add New User

Position Title:

*Email:

*Is the User a Direct Employee of:
Keller and Heckman LLP

Title:
- Select -

*Privileges: (0)

CTP Portal View Submission-Related Information

CTP Portal View/Reply Messages

CTP Portal View Only Messages

CTP Portal Upload

CTP Portal User Admin

*First Name:

Middle Name:

*Last Name:

Generational Suffix:
- Select -

Professional Suffix:

Time Zone:
(UTC-5:00) Eastern Standard Time (America/New_York)

Yes No, the user is an agent

Cancel Save

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- 5) If you are editing the privileges of a current user, select ALL privileges, except “CTP Portal User Admin.” (Emma McIntyre is the IAM for Keller and Heckman which is why she has “CTP Portal User Admin” selected).

CTP Portal | McIntyre, Emma | Keller and Heckman LLP | A2 ? Logout

Home Admin

Admin

Manage Users Manage Employers

Edit User Details [Send User Account Reset](#)

Position Title:
Practice Group Manager

Title:
- Select -

***First Name:**
Emma

Middle Name:

***Last Name:**
McIntyre

Generational Suffix:
- Select -

Professional Suffix:

Email: mcintyre@khlaw.com

Username: emma.mcintyre@kah

User Status:
Active
- Change -

Status Last Updated On:
12/01/2016 09:16 PM

***Privileges: (5)**

- ☒ CTP Portal View Submission-Related Information
- ☒ CTP Portal View/Reply Messages
- ☒ CTP Portal View Only Messages
- ☒ CTP Portal Upload
- ☒ CTP Portal User Admin

***Is the User a Direct Employee of:**
Keller and Heckman LLP
☒ Yes ☐ No, the user is an agent

Mailing Address:
☐ Same as: Keller and Heckman LLP

***Mailing Address Line 1:**
1001 G St NW Ste 500

Mailing Address Line 2:
Suite, floor, building, etc.

***Country:**
United States of America

***City:**
Washington

***State/Province:**
District of Columbia

Zip/Postal Code:
20001 - 4545

Country Code:
United States of America (+1)

Office Phone:
Ext

Office Fax:

Cancel Save

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6) Once you have changed a user's privileges, his/her homepage should update accordingly:

The screenshot displays the CTP Portal interface. At the top, a dark header bar contains the text "CTP Portal" on the left, the user "McIntyre, Emma" and firm "Keller and Heckman LLP" in the center, and a "Logout" button on the right. Below the header is a navigation bar with four tabs: "Home" (highlighted with a red box), "Messages 0", "Submissions", and "Admin". To the right of the navigation bar is a "Launch Upload Tool" button, also highlighted with a red box and pointed to by a green arrow. The main content area begins with a "Welcome to the CTP Portal" section, followed by a paragraph explaining the portal's purpose. Below this is a "Recent Regulatory Letters" section with a message "No Regulatory Letters exist." and a "Recent Notifications" section. The notifications list two items: "10/13/2016 09:44 AM" with a link "TC0001623" and "08/26/2016 09:29 AM" stating "The CTP Portal User Admin has changed". A "Let's Get Started" button is located at the bottom right of the welcome section. At the bottom of the page is a "Recent Uploads" section with the message "No Uploads exist.".

CTP Portal

McIntyre, Emma | Keller and Heckman LLP

Logout

Home Messages 0 Submissions Admin

Launch Upload Tool

Welcome to the CTP Portal

The U.S. Food and Drug Administration's (FDA), Center for Tobacco Products (CTP) developed the CTP Portal as part of its initiative to improve submission processing and facilitate interaction with industry stakeholders. The CTP Portal allows industry stakeholders to use the embedded upload feature to transmit eSubmitter-generated submissions; this new transmission method offers industry stakeholders an alternative to the Agency's existing WebTrader Hosted Solution.

The CTP Portal is intended for use by stakeholders in the regulated tobacco industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

The CTP Portal does not replace existing FDA systems and corresponding requirements, including but not limited to Tobacco Registration and Product Listing submissions made via the FDA Unified Registration Listing Systems (FURLS).

Let's Get Started

Recent Regulatory Letters

No Regulatory Letters exist.

Recent Notifications

10/13/2016 09:44 AM [TC0001623](#)
A submission is now available for viewing in the CTP Portal

08/26/2016 09:29 AM
The CTP Portal User Admin has changed

Displaying 2 most recent

Recent Uploads

No Uploads exist.

3. Download eSubmitter:

There is no need to wait until the CTP Portal Access is established or the Portal is properly formatted to continue working on ingredient listings. The portal is used for submission of information that is packaged using FDA's free eSubmitter tool. The eSubmitter tool is accessed via your desktop and has submission templates that include:

- Listing of Ingredients in Tobacco Products (Sections 904(a)(1) and 904(c) of the Federal Food, Drug, and Cosmetic Act (FD&CA));
- Tobacco Health Documents (Sections 904(a)(4) and 904(c) of the Federal Food, Drug, and Cosmetic Act (FD&CA));
- Reporting Harmful and Potentially Harmful Constituents (Sections 904(a)(3) and 904(c) of the Federal Food, Drug, and Cosmetic Act (FD&CA));
- Product Applications (e.g. PMTA, Exemption from SE, SE);
- These submission templates are updated by FDA regularly. Available for your reference are three (3) user manuals that expound upon different aspects of eSubmitter as it relates to CTP submissions (See **Exhibits 1 – 3**). **Please contact Keller and Heckman for electronic copies of Exhibits 1 – 3.**

- 1) eSubmitter can be downloaded here: <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>.
- 2) Pay close attention to the file location
- 3) Put a shortcut on your desktop or pin to the start bar for ease of access

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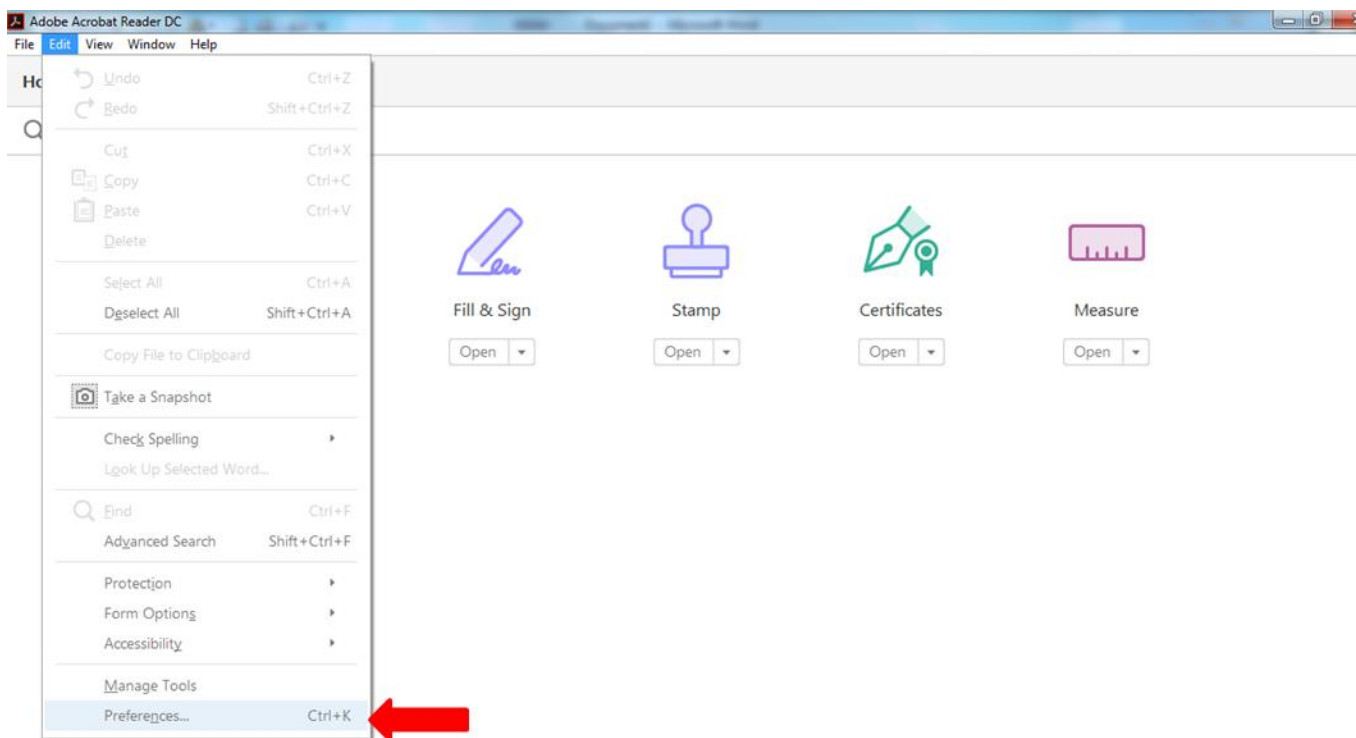
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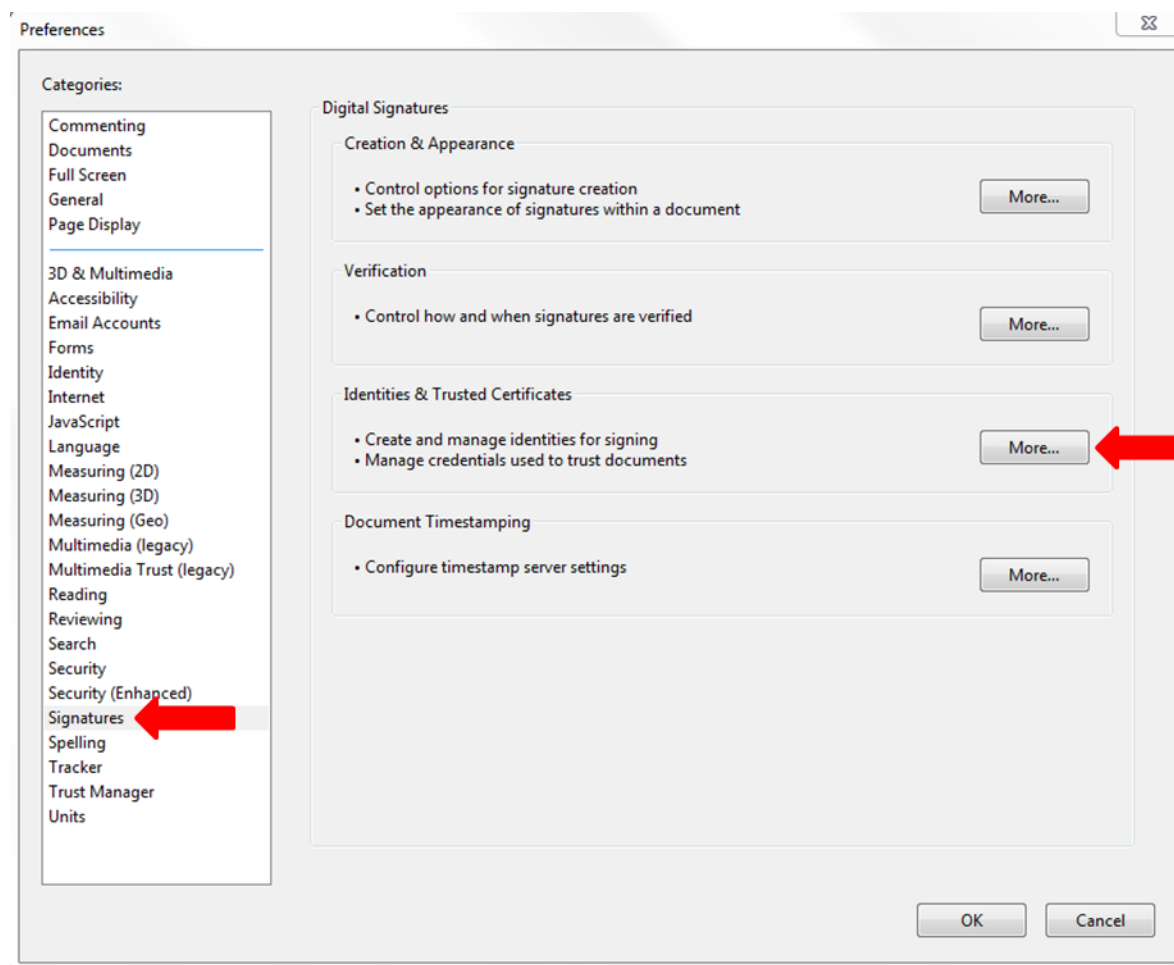
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4. Create a Digital Signature:

- 1) In Adobe (you can use Adobe Acrobat Reader, downloadable from <https://get.adobe.com/reader/>) go to “Edit” and select “Preferences” from the pulldown (indicated by the red arrow in the image below)



- 2) Select “Signatures” from the Categories list and then click “More” next to “Identities & Trusted Certificates” as indicated in the image below



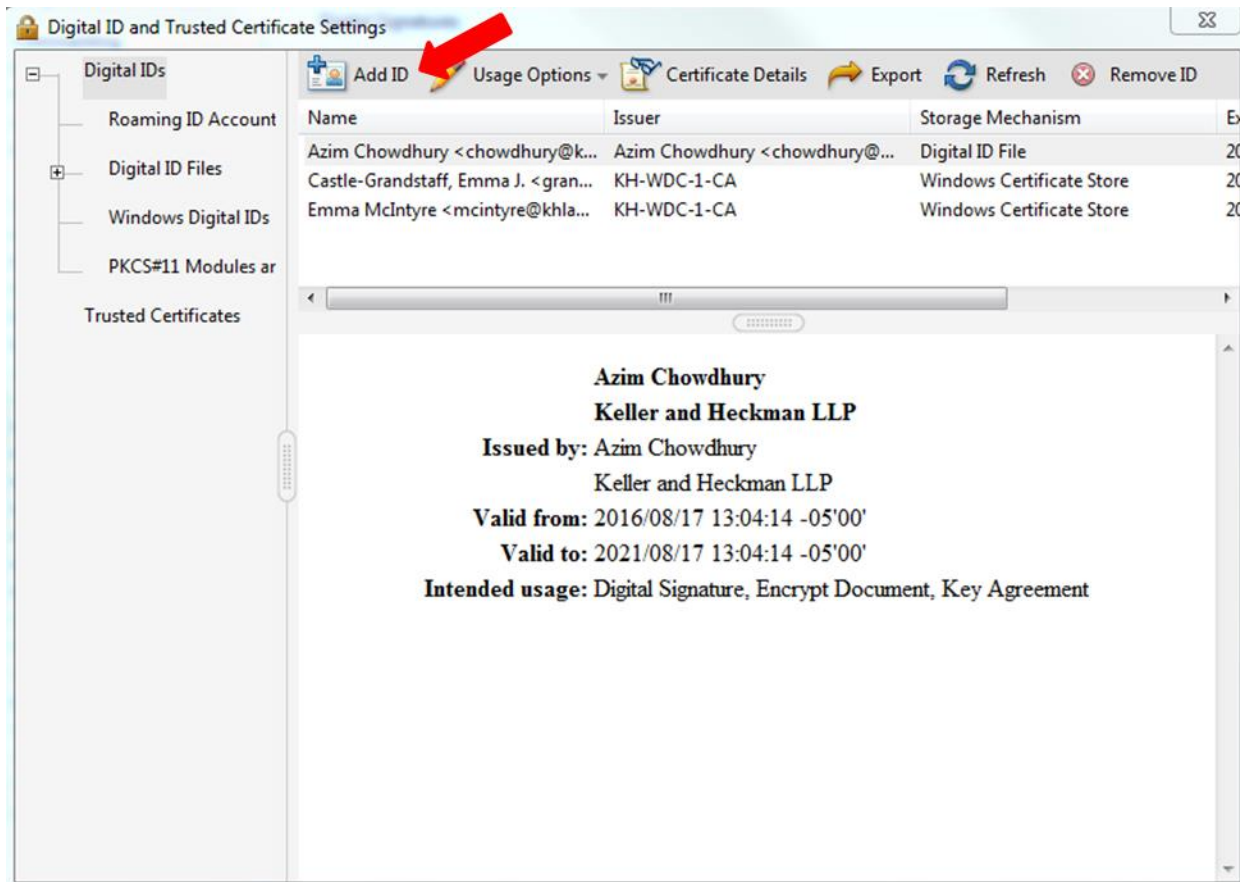
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3) Next select “Add ID” as indicated by the red arrow in the following image



4) Choose “A new digital ID I want to create now” and then “Next”

5) Choose “New PKCS#12 digital ID file” and then “Next”

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- 6) Fill in the information requested (Key Algorithm should be “1024-bit RSA” and Use digital ID for should be “Digital Signatures and Data Encryption”) and click Next
- 7) Select location to save the signature and assign a password. Click “Finish”

5. Collect Information to Enter in eSubmitter:

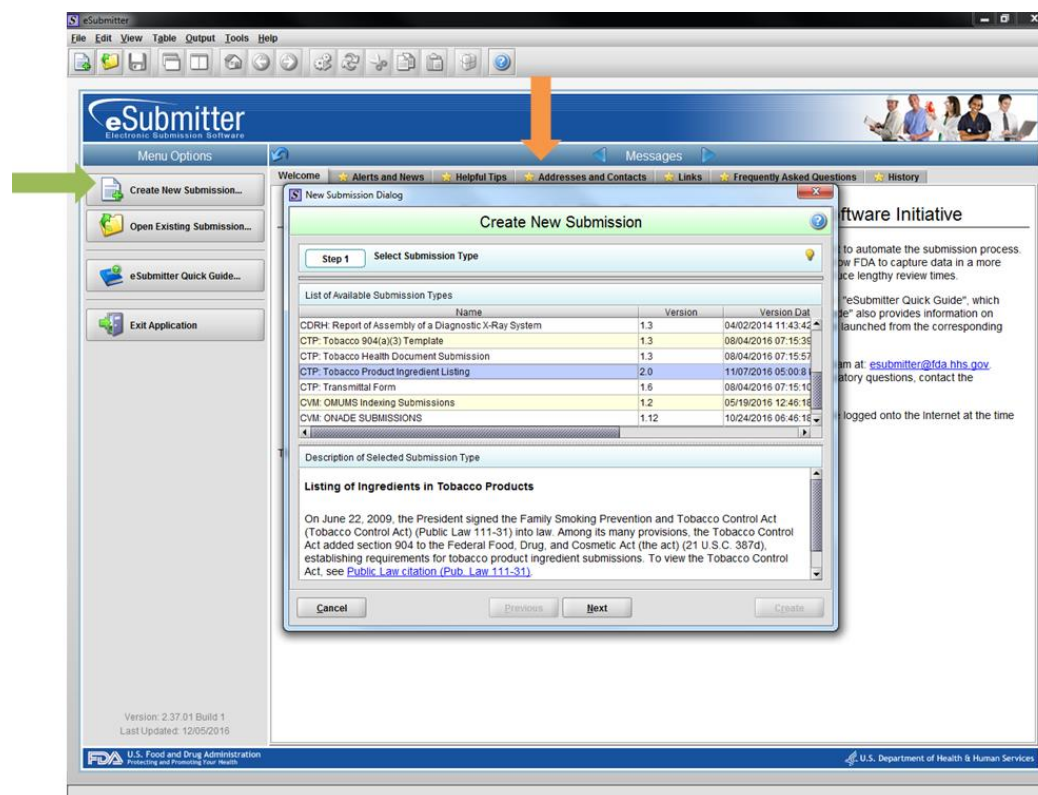
See our separate memorandum (“User Guide – Ingredient Listing of E-Liquids and E-Vapor Devices”) on what information should be collected.¹

- 1) There are FDA provided spreadsheets that can be used to enter the product and ingredient (but not component) information.
 - a. You can utilize these to help with uploading
 - b. Do not change the formatting
 - c. Save your completed work as a “.xls” and not as a “.xlsx” as eSubmitter will not look for a “.xlsx” file to upload

¹ 1)FDA has not, to date, provided any guidance on how to submit “ingredients” for e-vapor device hardware. None of the current guidance document, the eSubmitter template nor the Form 3742 provide any insight in this regard. In the absence of any such information from FDA, this memorandum provides our best assumptions for how to prepare ingredient listing reports for e-vapor devices. Please note that FDA could provide additional guidance on ingredient listing for either e-liquids or e-vapor devices in the future that could differ from the information presented herein. Where FDA is silent on a request or requirement we cannot guarantee that FDA’s expectation for reporting ingredients is consistent with these guidelines. We will, of course, update these guidelines as necessary if FDA provides more information.

6. Setting up eSubmitter and 7. Entering Ingredient Listings in eSubmitter

- 1) When you open up eSubmitter and click on “Create New Submission” (indicated by the green arrow in the picture) you will see the following:



Note that the orange arrow points to a series of starred tabs with helpful background information (available before you click on “Create New Submission”)

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- 2) Select “CTP: Tobacco Product Ingredient Listing” (highlighted in the picture above) and then click “Next”
- 3) On the next screen you will be prompted to provide a descriptive name and filename.

The screenshot displays the eSubmitter software interface. A 'New Submission Dialog' window is open, titled 'Create New Submission'. The dialog has a 'Step 2' tab selected, with the subtitle 'Provide Submission Details'. Below this, there is a section 'Specify the Submission Descriptive and File Names' containing two input fields: 'Descriptive Name' with the text 'Keller and Heckman Example E-Cigarette' and 'File Name (.xml)' with the text 'KH_E-Cig'. Below these fields is a text area for 'Additional Comments about this Submission'. At the bottom of the dialog are four buttons: 'Cancel', 'Previous', 'Next', and 'Create'. The background interface shows a menu on the left with options like 'Create New Submission...', 'Open Existing Submission...', 'eSubmitter Quick Guide...', and 'Exit Application'. The top of the interface has a menu bar with 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The bottom of the interface features the FDA logo and the text 'U.S. Food and Drug Administration' and 'U.S. Department of Health & Human Services'.

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Note that both the descriptive name and file name spaces have a blue dot next to them. The blue dot indicates a required field. If you click on the light bulbs throughout eSubmitter, you will get some additional information about the information requested.

- 4) After you click “Create” you will be taken to a page labeled “Screen View: Listing of Ingredients: Overview”
- 5) The first time you use eSubmitter, you should take the time to manage your address list and contact list

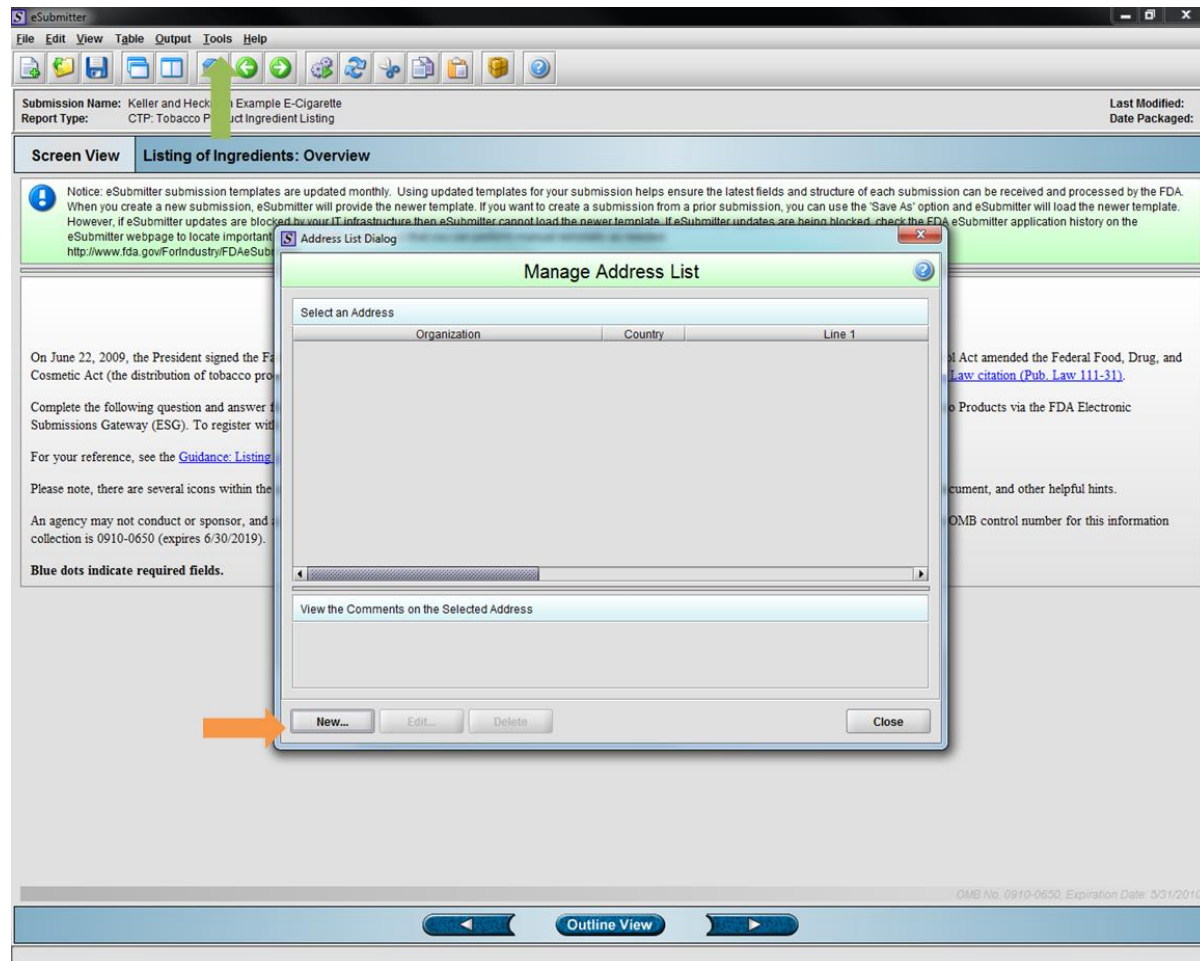
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- 6) To access the address and contact lists, go to “Tools” (indicated by the green arrow in the picture below) and choose the appropriate list from the pull down. In the image below, the address list has been accessed



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- 7) To add a new address, click “New” (indicated by the orange arrow in the picture above) and you will be brought to the following screen:

The screenshot shows the eSubmitter application window with the 'New Address Dialog' open. The dialog has three tabs: 'Organization Identification', 'Physical Location', and 'Mailing Location'. The 'Organization Identification' tab is selected, displaying the following fields:

- Organization Name: Keller Corp
- Division Name: (empty)
- Reference Numbers:
 - FDA Establishment Identifier (FEI): (empty)
 - Central File Number (CFN): (empty)
 - D&B D-U-N-S Number: (empty)
 - Registration Number: (empty)
 - Owner/Operator Number: (empty)
- Internet Home Page Address: (empty)
- Organization Comments: (empty text area)

At the bottom of the dialog are 'OK' and 'Cancel' buttons. In the background, an orange arrow points to the 'New' button in the 'Listing of Ingredients: Overview' screen. Two blue arrows point to the 'Physical Location' and 'Mailing Location' tabs in the dialog.

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Note that the Organization Name is “Keller Corp” (indicated by the orange arrow in the picture above) but that none of the reference numbers (indicated by the green arrow in the picture above) have been filled in. If Keller Corp had any of these numbers they would also have been filled in, but they are not necessary at this time.

- 8) Click on the middle tab (“Physical Location”; indicated by the leftmost of the two blue arrows in the picture above) to fill in the location information, as displayed below:

The screenshot displays the eSubmitter application interface. At the top, the submission details are shown: Submission Name: Keller and Heckman Example E-Cigarette, Report Type: CTP: Tobacco Product Ingredient Listing, Last Modified: 12/29/2016 11:27:15 AM, and Date Packaged: . The main window has a tabbed interface with 'Screen View' and 'Listing of Ingredients: Overview'. A dialog box titled 'Edit Address Dialog' is open, showing the 'Physical Location' tab. The dialog has three tabs: 'Organization Identification', 'Physical Location', and 'Mailing Location'. The 'Physical Location' tab contains the following fields: Country (United States of America), Address - Line 1 (1001 G St N.W. Suite 500 West), Address - Line 2, City (Washington), State, Province, or Territory (District of Columbia), Post Office or Zip Code (20001-), Phone Numbers (Telephone number: (202) 434-4103 Ext, Fax number: () - -), and OK/Cancel buttons. The background application window shows a sidebar with various links and a main content area with text about the Federal Food, Drug, and Cosmetic Act.

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- 9) Click on the “Mailing Location” tab. If the Physical and Mailing Locations are the same, you can check the “Copy Address” button (indicated by the green arrow in the picture below) to import the information from the Physical Address into the Mailing Address fields. Otherwise, fill in the Mailing Location

The screenshot shows the eSubmitter application window. The main window has a menu bar (File, Edit, View, Table, Output, Tools, Help) and a toolbar. Below the menu bar, there is a status bar showing the Submission Name: Keller and Heckman Example E-Cigarette, Report Type: CTP: Tobacco Product Ingredient Listing, Last Modified: 12/29/2016 11:27:15 AM, and Date Packaged: . The main content area is titled 'Screen View Listing of Ingredients: Overview'. A dialog box titled 'Edit Address Dialog' is open, showing the 'Mailing Location' tab. The dialog box has a 'Copy Address' button and a 'Copy the physical location to the mailing location' checkbox. The 'Address' section contains fields for Country (United States of America), Address - Line 1 (1001 G St N.W., Suite 500 West), Address - Line 2, City (Washington), State, Province, or Territory (District of Columbia), and Post Office or Zip Code (20001-). The 'Phone Numbers' section contains fields for Telephone number ((202) 434-4103 Ext.) and Fax number (). A green arrow points to the 'Copy Address' button. The dialog box also has 'OK' and 'Cancel' buttons at the bottom.

Note: the more information you can provide, the better. Phone number may be especially helpful

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- 10) At a minimum, you should enter Organization information for the manufacturer, the authorized representative, and the US Agent
- 11) Once you have completed entering organizations, you can move on to contacts. You will be able to import addresses for contacts using the information in the organizations, so it is important that you enter your organizations first

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Keller and Heckman Example E-Cigarette
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified: 12/29/2016 02:44:27 PM
Date Packaged:

Screen View Listing of Ingredients: Overview

Notice: eSubmitter submission templates are updated monthly. Using updated templates for your submission helps ensure the latest fields and structure of each submission can be received and processed by the FDA. When you create a new submission, eSubmitter will provide the newer template. If you want to create a submission from a prior submission, you can use the 'Save As' option and eSubmitter will load the newer template. However, if eSubmitter updates are blocked by your IT infrastructure then eSubmitter cannot load the newer template. If eSubmitter updates are being blocked, check the FDA eSubmitter application history on the eSubmitter webpage to locate important information.
<http://www.fda.gov/ForIndustry/FDAeSubmitter>

Edit Contact Dialog

Contact Identification Organization Identification Physical Location Mailing Location

Contact

Title (e.g., Mr., Ms.): Mr.
First/Given Name: Benjamin
Middle Name:
Last Name: Wolf
Suffix (e.g., Sr., Jr., III):
Degree(s) (e.g., PhD, JD): J.D.
Occupation Title: Attorney
Email Address: wolf@khlaw.com

Contact Comments

OK Cancel

Outline View

OMB No. 0910-0650, Expiration Date: 5/31/2019

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Note that there are four tabs (indicated by the orange arrow in the picture above). You will be able to import information from an already entered organization in much the same way as you were able to copy the physical and mailing address of an organization. Otherwise you will have to populate the fields within these tabs as described above.

- 12) At a minimum, you should enter contact information for the manufacturer, the authorized representative, and the US Agent
- 13) Once you have completed entering your contacts, click on the right blue arrow (near the bottom of the page, indicated by the green arrow in the image above)

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- 14) You will be taken to a screen asking for submission type. If you have not previously provided an ingredient list to FDA, you should select the first choice (indicated by the orange arrow in the picture below)

The screenshot shows the eSubmitter application window. The title bar is 'eSubmitter'. The menu bar includes File, Edit, View, Table, Output, Tools, and Help. The toolbar contains various icons for file operations. The main window has a header section with 'Submission Name: Keller and Heckman Example E-Cigarette' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. Below this is a tabbed interface with 'Screen View' and 'Listing of Ingredients: Submission Type'. The 'Submission Type' tab is active, displaying a form titled 'Submission Type'. The form contains instructions for selecting a submission status. An orange arrow points to the first radio button option: '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)'. Other options include '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)*', and 'Type f: Amendment to correct previous product ingredient submission(s)**'. At the bottom, there is a field for 'Enter the previous product ingredient submission tracking number.' and a button labeled 'Outline View'.

Submission Name: Keller and Heckman Example E-Cigarette
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:

Outline View

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- 15) Advance to the next screen using the right blue arrow and then check the box indicating that you are a “Manufacturer” (or agent for a manufacturer; unless the form is being completed by an importer or agent of an importer, in which case you should select “Importer”)
- 16) Advance to the next screen using the right blue arrow. There is no information you need to enter on this screen
- 17) Advance to the next screen using the right blue arrow
- 18) You will be prompted to enter company and contact information at this point
- 19) If you did not create a contact before, you can still create one now, by going to the “Tools” menu and following the instructions above

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- 20) You can click on the import button (indicated by the orange arrow in the picture below) and then follow the prompts to select which contact to import

The screenshot shows the eSubmitter software interface. The main window is titled 'eSubmitter' and has a menu bar with 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. Below the menu bar is a toolbar with various icons. The main area is divided into two panes. The left pane is titled 'Screen View' and contains a 'Listing of Ingredients: Submitter Identification' section. The right pane is titled 'Listing of Ingredients: Submitter Identification' and contains a form for entering contact information. An orange arrow points to the 'Import' button in the top right corner of the right pane. A 'Contact List Dialog' is open in the center of the screen, displaying a table of contacts. The table has columns for 'Contact Name', 'Occupation Title', and 'Org'. The contacts listed are: Wolf, J.D., B. (Attorney, Heckman LLC), Wolf, J.D., Ben (Attorney, KHLaw), and Wolf, J.D., Benjamin (Attorney, Keller Corp). The dialog also has buttons for 'New...', 'Edit...', 'Delete', 'Select', and 'Close'.

Submission Name: Keller and Heckman Example E-Cigarette
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified: 12/29/2016 02:44:27 PM
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:

Company Headquarters FDA:

Organization URL (e.g., www.):

Company Mailing Address:

Country:

Address - Line 1:

Address - Line 2:

City:

State:

State, Province, or Territory Name:

Zip or Postal Code:

Authorized Representative (First Name):

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:

United States

1001 G St N.W., Suite 500 West

Washington

District of Columbia

20001-

Benjamin

Wolf

J.D.

Attorney

wolf@khlaw.com

Select from Contact List

Select a contact

Contact Name	Occupation Title	Org
Wolf, J.D., B.	Attorney	Heckman LLC
Wolf, J.D., Ben	Attorney	KHLaw
Wolf, J.D., Benjamin	Attorney	Keller Corp

View comments on the selected contact

New... Edit... Delete Select Close

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eSubmitter

File Edit View Table Output Tools Help

Submission Name: Keller and Heckman Example E-Cigarette
Report Type: CTP: Tobacco Product Ingredient Listing

Last Modified: 12/30/2016 10:26:17 AM
Date Packaged:

Screen View **Listing of Ingredients: Submitter Identification**

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

Position Title: Attorney

Email Address: wolf@khlaw.com

Telephone Number(s):

2 of 4 items in the list

(202) 434-4103; US, Office

(202) 434-4103; US, Office

Fax Number:

0 of 1 items in the list

Mailing Address for the Authorized Representative (Responsible official authorized to represent the submitter)

Is the Authorized Representatives' Company Information the same as above? ☒ Yes ☐ No

Company Name:

Country:

Address - Line 1:

Address - Line 2:

City:

State:

State, Province, or Territory Name

Zip or Postal Code:

Outline View

Note that we checked that the Mailing Address for the Authorized Representative is the same as above. Otherwise you can enter additional information.

21) Importing the contact will autofill the information on the page (already completed in the images above)

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- 22) If you choose not to import, you can hand enter all required information
- 23) After you click the right blue arrow to go to the next page, you will be asked to fill in the information for the U.S. Agent. Completing this information is the same as completing the information for the submitter identification and is required by the system regardless of where your company is located
- 24) After you click the right blue arrow to go to the next page, you will be brought to a page where no information needs to be added. Click the right blue arrow again to move to the next page

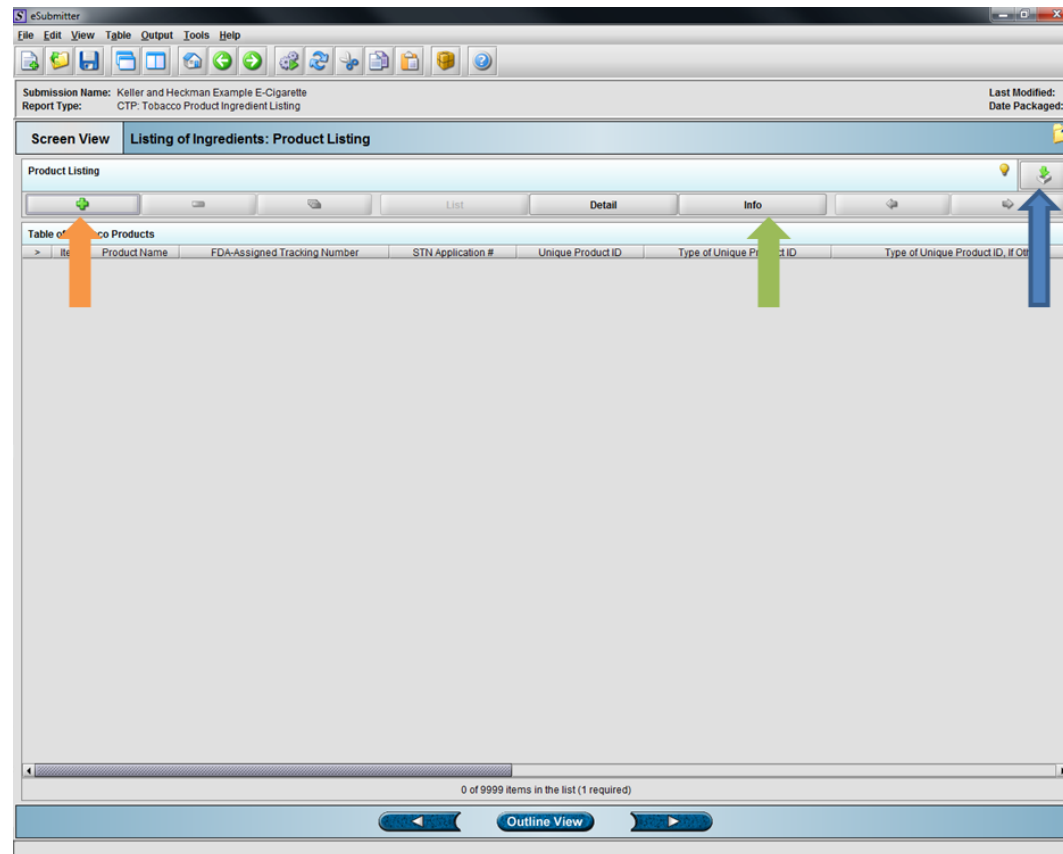
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25) You will now be prompted to list your products by clicking on the green plus (indicated by the orange arrow in the image below) or clicking on the file import icon (indicated by the blue arrow in the image below)



Note that we are uploading an example vaping device, but the mechanics of entry will remain the same regardless of product type.

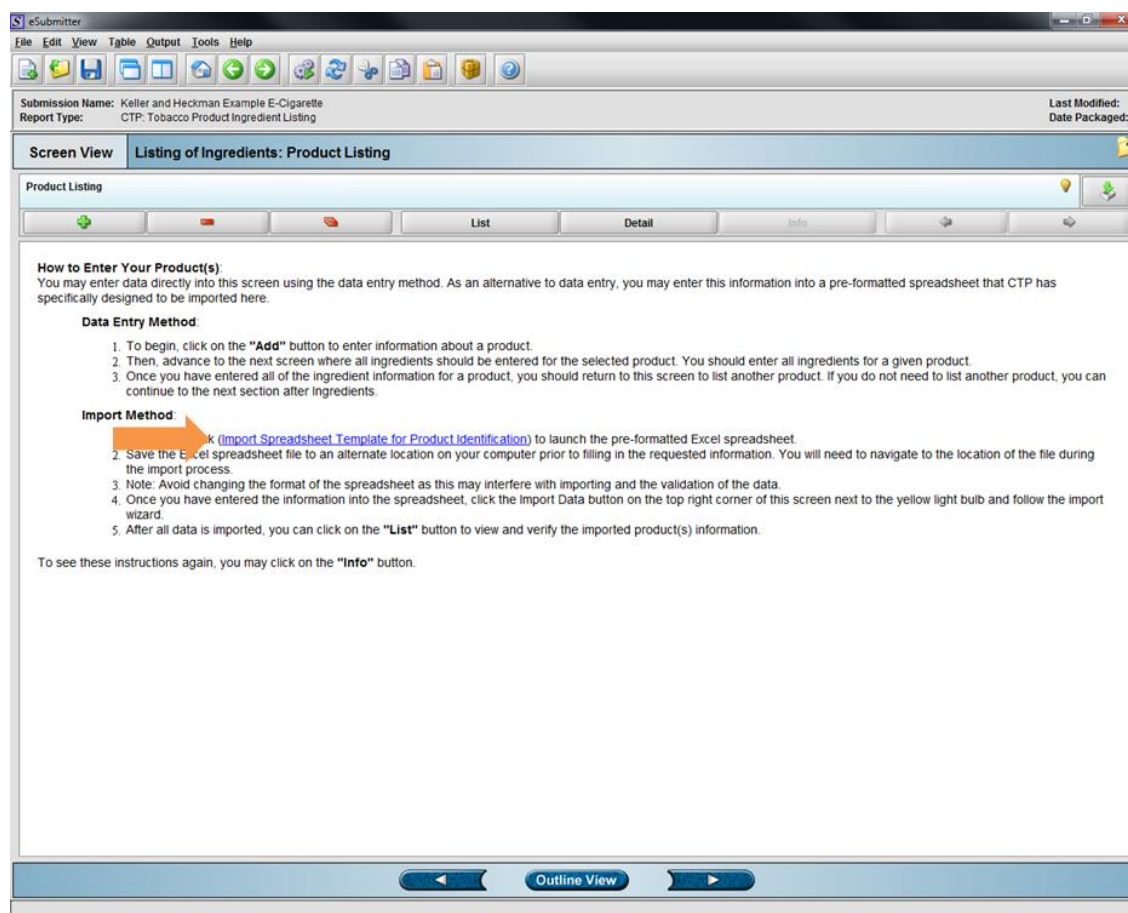
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26) The link to download the spreadsheet can be found by clicking on the “Info” button (indicated with the green arrow in the image above) and then clicking on the hyperlinked text (indicated with the orange arrow in the image below).



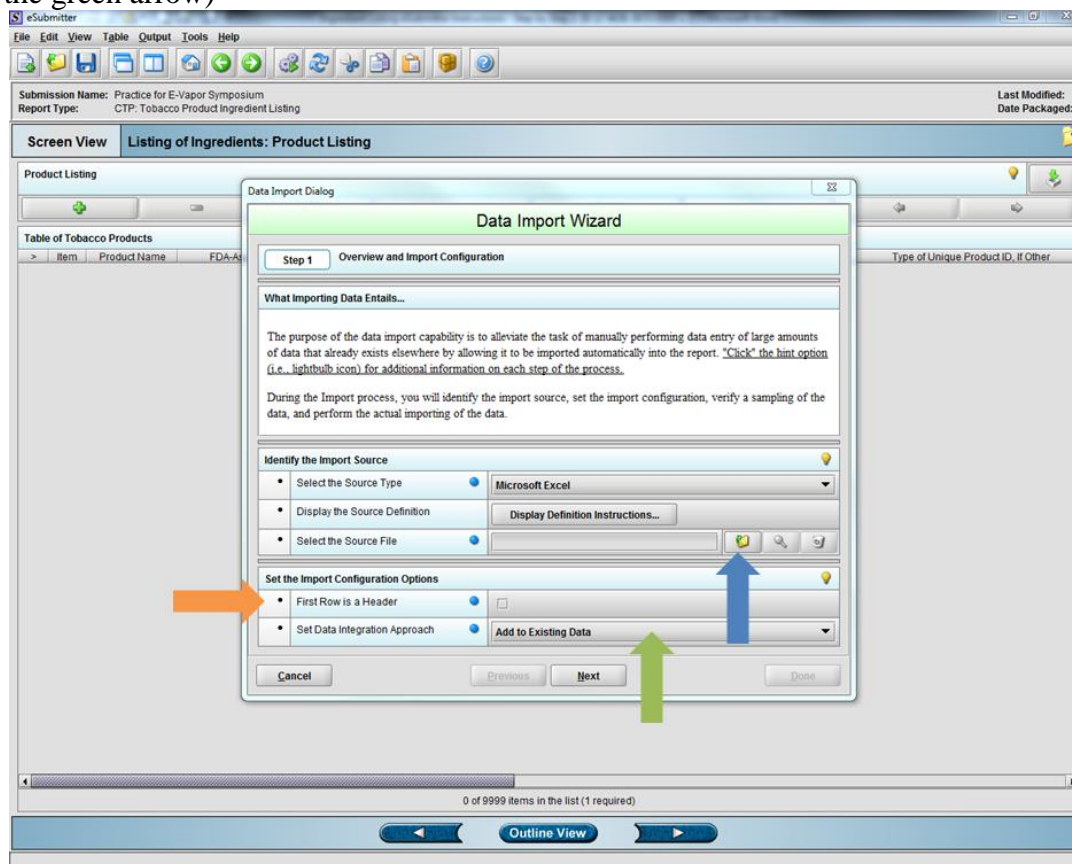
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- 27) After selecting the import icon, a pop-up window will come up in which you can select the file to import (see image below; the blue arrow indicates the icon to select the file; the checkbox should be checked next to “First Row is a Header” (indicated by the orange arrow) and you should determine whether to add the imported data to the existing or to overwrite what you have already inserted (see the green arrow)



Note that you might wish to add the imported data rather than overwrite if you reach the limit on rows per spreadsheet.

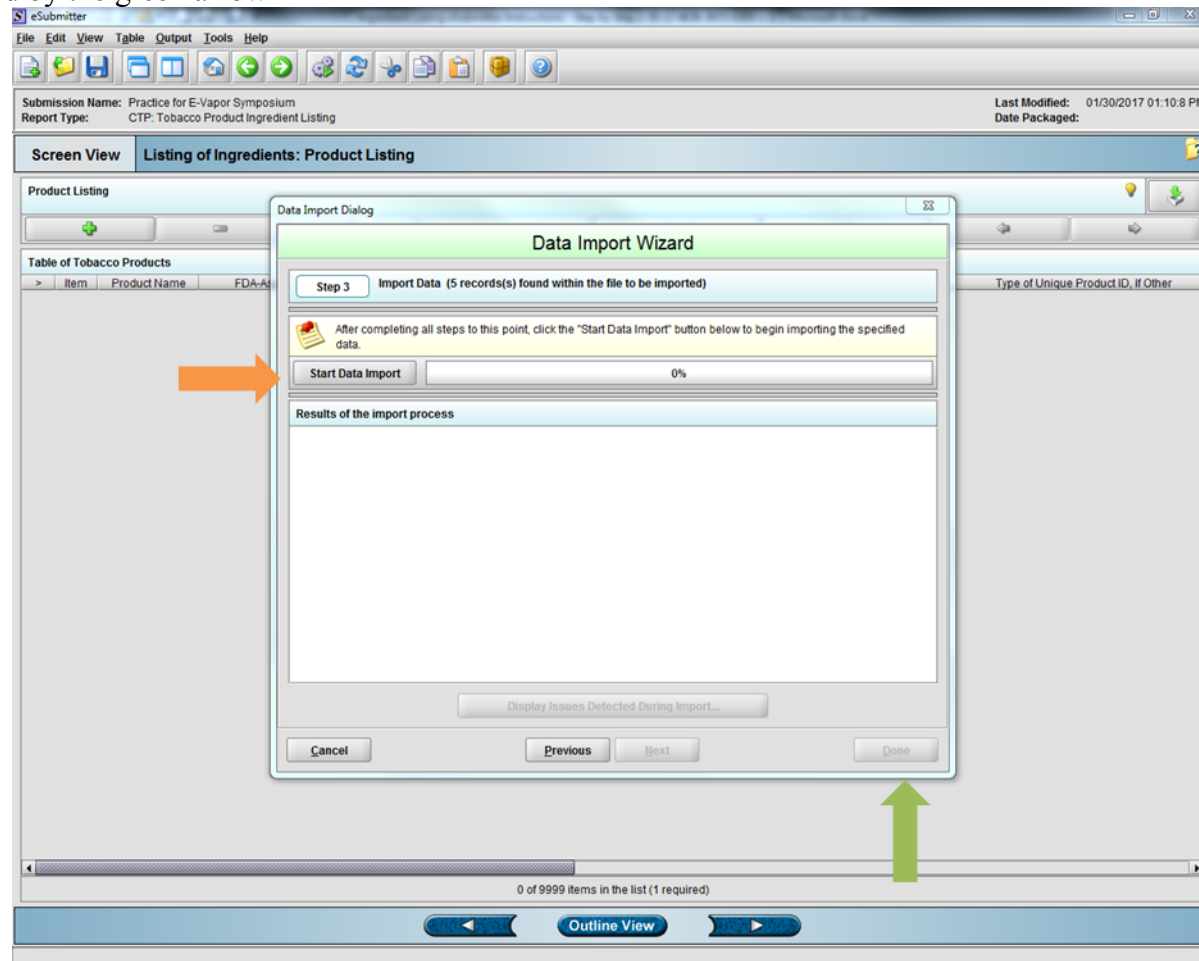
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- 28) After you hit “Next” on the pop-up, you will be given an opportunity to review the data. Hit “Next” a second time and you will get the screen in the image below. You should click “Start Data Import” (indicated by the orange arrow) and then click “Done” indicated by the green arrow



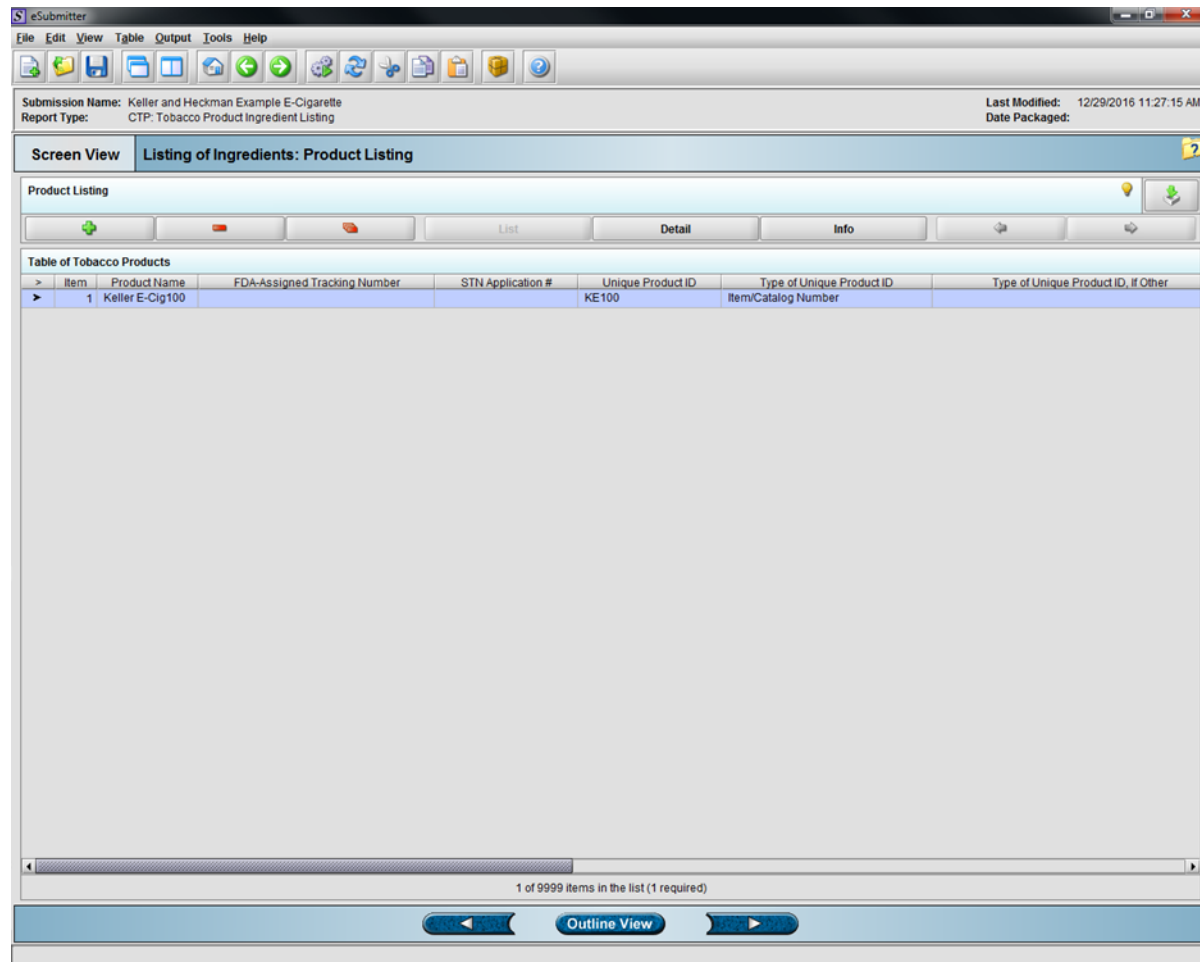
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29) After importing the product list (ours only had one product), your screen will look like this:



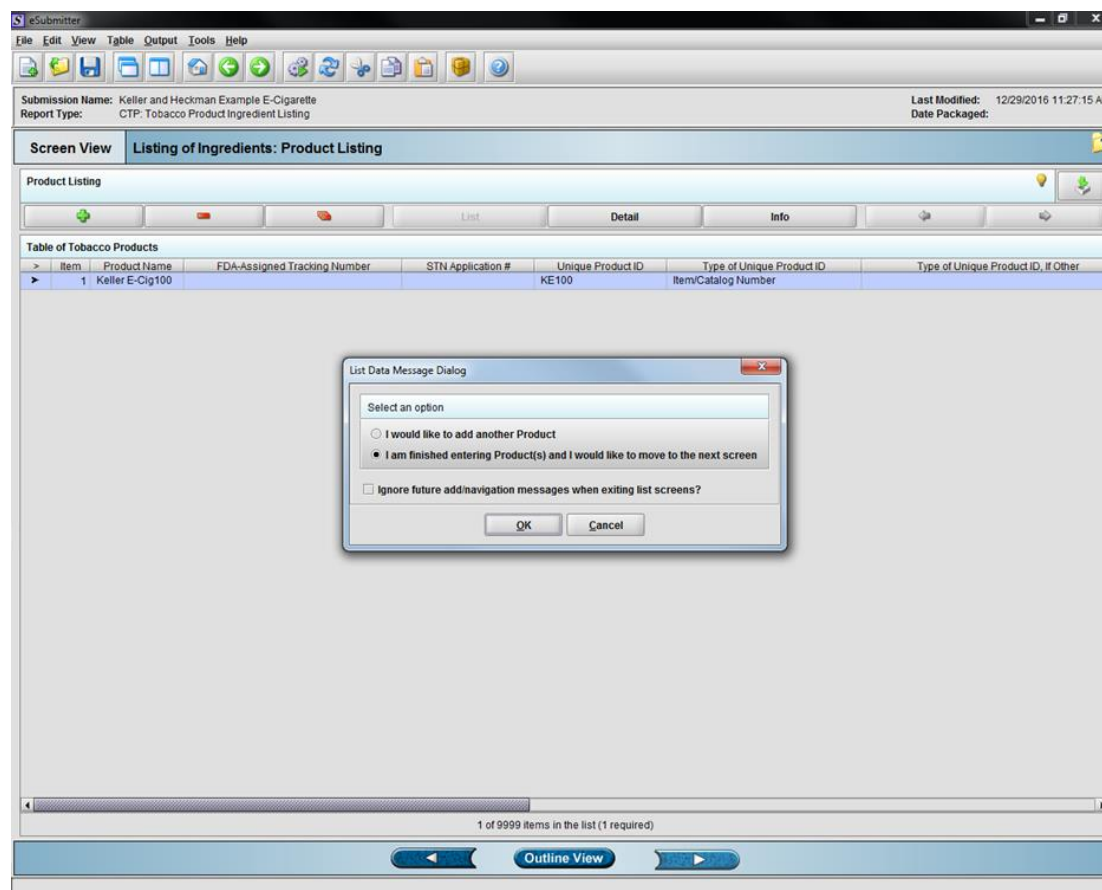
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- 30) When you click the right blue arrow to move to the next screen, you will get a popup box asking you to make a selection before moving on (see image below). This warning comes up any time you can enter product, component, or ingredient information as a reminder that you may wish to enter more information. You can just click “OK” and move on. If you want to come back later, you may



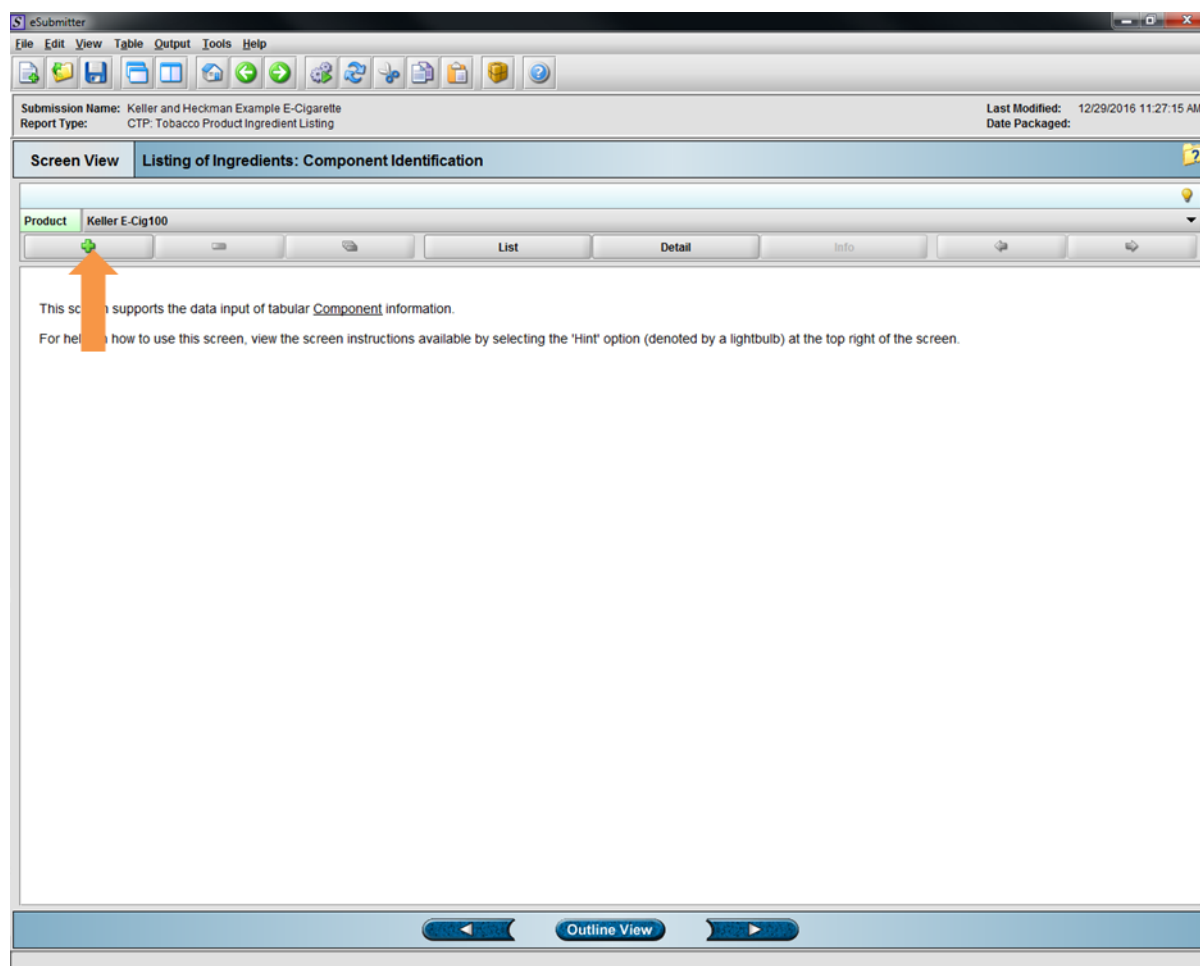
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31) Next you will need to enter component information by clicking on the green plus (indicated by the orange arrow in the image below). Note that there is no option for importing a list of components



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- 32) The next image shows the page for listing a component. You need to indicate component type (indicated with the orange arrow; here “Coil/Coil Head”), name the component (indicated with the green arrow; here “3.0 Ohm Coil Head”) and you need to provide manufacturer information and item number by checking the green plus near the bottom of the page (indicated by the blue arrow) and filling in the information in the box that comes up

eSubmitter

File Edit View Table Output Tools Help

Submission Name: Keller and Heckman Example E-Cigarette
Report Type: CTP: Tobacco Product Ingredient Listing
Last Modified: 12/29/2016 11:27:15 AM
Date Packaged:

Screen View Listing of Ingredients: Component Identification

Product: Keller E-Cig100

Item: 1

All tobacco products contain at least one component. Enter the component(s) for each product. Use the product drop-down above to enter the components for each product.

Component Type: Coil/Coil Heads

Component Name (e.g., Name/type of adhesive, such as Cigarette Rod Adhesive, Tipping Adhesive, Filter Seam Adhesive, Anchor Line Adhesive; or Name/type of tobacco filler additive, such as Casing Tobacco Filler Additive, Top Flavoring Tobacco Filler Additives): 3.0 Ohm Coil Head

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

Add Mfr. Name and Item Identifier Dialog

Mfr. Name and Item Identifier: Keller Corp KE30SS

OK Cancel

Outline View

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- 33) After listing all components (we also listed a component for the mouthpiece) you will advance until you reach the ingredient listing tab. Select the component for which you wish to import ingredients (or enter ingredients) by clicking on the grey box next to the word component (indicated with an orange arrow in the picture below) and selecting the component

The screenshot shows the eSubmitter 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 'Listing of Ingredients: Ingredient Listing' screen. At the top, it shows 'Submission Name: Keller and Heckman Example E-Cigarette' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. The 'Screen View' tab is active. Below this, the 'Ingredient Listing By Product' section shows 'Product: Keller E-Cig100' and 'Component: Coil/Coil Heads; 3.0 Ohm Coil Head'. An orange arrow points to the 'Component' dropdown menu. Below the dropdown, a table titled 'Table of Ingredient Specifications' is displayed. The table has columns: Item, Ingredient Name, Ingredient Number, Ingredient Type, Unique Scientific Name or Code, Type of Name, Type of Name, If Other, Registry Code, and Type. The table contains four rows of data. At the bottom of the window, a status bar indicates '4 of 9999 Items in the list (1 required)' and there are navigation buttons for 'Outline View'.

Item	Ingredient Name	Ingredient Number	Ingredient Type	Unique Scientific Name or Code	Type of Name	Type of Name, If Other	Registry Code	Type
1	Coil Wire	KE30SSWire	Complex Ingredients					
2	Silicon Seal	KESiliconSeal	Complex Ingredients					
3	Cap	KE100Cap	Complex Ingredients					
4	Case	KE100Case	Complex Ingredients					

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- 34) You can now enter (by clicking the green plus) or import (by clicking the file import icon) in the same way you did for entering or importing product information.
- 35) Note that in the image above, the list view is selected (this is obscured by the pull down box for “Component”). In this view you can click on each ingredient to view it and enter/edit information
- 36) If you have a complex purchased ingredient that is custom made to your specifications, FDA requires that you identify which ingredients are made to your specifications.
 - a. You can submit your ingredient listing to FDA at this time without providing other specifications (aside from ingredients)
 - b. You should also gather any technical drawings and other documents used for specifications like release specifications, acceptance criteria, a sample certificate of analysis, but this is not required to be submitted
 - c. You will not be able to package your submission without listing the ingredients, however we believe that you can list an ingredient as its own specified ingredient (in our hypothetical case, the mouthpiece is a complex purchased ingredient made to specification out of wood and resin epoxy but we list KE100 Mouthpiece as the specified sub-ingredient for the complex purchased ingredient KE100 Mouthpiece; see screenshot below)
 - d. After you have uploaded the ingredient list for the component that contains the ingredient, you will need to confirm that the box for “Yes” in response to the question “Is this ingredient custom made to your specifications?” is checked (see orange arrow in the image below) and you will need to list the ingredients used in your custom made ingredient

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The screenshot shows the eSubmitter application window. The title bar reads 'eSubmitter'. The menu bar includes 'File', 'Edit', 'View', 'Table', 'Output', 'Tools', and 'Help'. The status bar at the top right shows 'Last Modified: 01/10/2017 03:27:23 PM' and 'Date Packaged: 12/30/2016 11:48:50 AM'. The main content area is titled 'Listing of Ingredients: Ingredient Listing'. It features a 'Product' dropdown set to 'Keller E-Cig100' and a 'Component' dropdown set to 'Mouthpiece; KE100 Mouthpiece'. Below these are buttons for 'List', 'Detail', and 'Info'. A modal dialog titled 'Ingredient Name/Identifier Selection Dialog' is open, displaying a list with 'KE100 Mouthpiece' selected. The dialog has 'Select' and 'Cancel' buttons. In the background, the 'Item: 1' section includes fields for 'Type', 'Variety', 'Cure Method', 'Heat Source', and 'Describe any DNA recombinant technology used to engineer...'. There is a section for 'Complex Ingredients' with a text area and a green plus icon. Below this is a question 'Is this ingredient custom made to your specifications?' with 'Yes' and 'No' radio buttons. An orange arrow points to the 'Yes' button. Below that is a section 'If Yes, enter each specified ingredient by clicking on the plus (+) sign.' with a green plus icon and a green arrow pointing to it. The bottom of the screen shows 'PART 2: INGREDIENT DETAILS' and navigation buttons.

37) To list the ingredients in a custom ingredient, click the green plus after “If Yes, enter each specified ingredient by clicking on the plus (+) sign” (indicated by a green arrow in the picture above) and then select the specified sub- ingredients that are

included in the custom ingredient by clicking on each ingredient that is included while holding down the ctrl key and then clicking select

- a. We believe that you can enter the ingredient itself as its own specified sub-ingredient (i.e. in our example we did not include the ingredients walnut wood and resin epoxy and we selected the complex purchased ingredient (KE100 Mouthpiece) as the specified sub-ingredient for itself).
- b. FDA may request additional information in the future if you do not list all specified ingredients as part of a custom complex purchased ingredient
- c. To provide FDA with all specified ingredients, enter the specified ingredients at the same time and in the same way you would enter ingredients for a particular component. You will have to provide all of the same information as you would for an “off-the-shelf” complex purchased ingredient or single chemical entity. When you select the specified ingredients by clicking on the green plus indicated by the green arrow in the picture above), all ingredients listed for the component (including the specified ingredients you listed) will be available to select and you can choose the appropriate specified ingredients in the same way described above

38) Note that in the image above, the “Detail” view has been selected. In this view each ingredient will be on the same page and can be accessed by scrolling up and down

39) After moving forward using the right blue arrow twice, you will come to a page for entering other products that are identical on a unit-by-unit basis but for the packaging and packaging configuration (including labeling). This would apply if you were selling items as a single or multi-unit option or if you overlabel for multiple companies as a contract manufacturer.

Remember, if the change in packaging results in a change to the product inside, this is a new product that must have its ingredients listed separately

- a. Also note, the change in labeling or packaging likely means each product must be listed separately as part of the registration and listing process (currently US only) even if the product inside the packaging is identical

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- 40) To list identical products, click the green plus sign and enter the information requested (see the image below, green plus sign indicated by an orange arrow)
- Note that each product must be listed manually, there is no import option

The screenshot shows the eSubmitter 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 data management. The main window has a header section with 'Submission Name: Keller and Heckman Example E-Cigarette' and 'Report Type: CTP: Tobacco Product Ingredient Listing'. On the right, it shows 'Last Modified: 12/29/2016 01:07:18 PM' and 'Date Packaged:'. Below this is a tabbed interface with 'Screen View' and 'Listing of Ingredients: Identical Product Information'. The 'Product' dropdown menu is set to 'Keller E-Cig100'. An orange arrow points to a green plus sign icon in the dropdown menu. Below the dropdown is a section titled 'Item:' with a text area for description. A tooltip is visible over the text area, stating: 'By clicking the plus sign, you may record the identification information for any tobacco product(s) that you manufacture that are identical to the product listed in the previous screen other than packaging differences that do not affect the characteristics of the product. You do not then need to submit separate ingredients listings for each of the products. Use the product drop-down above to enter the information for the identical product(s)'. Below the text area are several input fields: 'Tobacco Product Brand/Sub-brand Name or Other Commercial Name (e.g., Acme Lights 100's or Acme Reconstituted Tobacco #202):' with the value 'Keller E-Cig100 3 Pack'; 'FDA Assigned Tobacco Product Tracking Number (TP#####):' with the value '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):' with the value 'KE1003pk'; 'Product Identification Number (At least one product identification number must be provided if needed to uniquely identify the product.):' with the value 'KE1003pk'; and 'Select the type of product identification number:' with the value 'Item/Catalog Number'. At the bottom, there is a button labeled 'Outline View'.

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- 41) After you advance forward, you will get to a page that allows you to upload a cover letter (indicated by the green arrow) or other information (including specifications for custom ingredients, etc.). These are not required, but we would recommend providing a cover letter (not included in our example)

The screenshot displays the eSubmitter 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. The main content area is titled 'Listing of Ingredients: Additional Information' and includes a yellow informational banner about spreadsheet imports. Below this, the 'Cover Letter' section prompts the user to attach a cover letter, with a 'File Attachment' button highlighted by a green arrow. The 'Additional Submission Documents' section prompts the user to attach relevant documentation, with a file upload button highlighted by an orange arrow. The 'Submission Comments' section provides a text area for user comments. The footer includes the OMB No. 0910-0650 and Expiration Date: 5/31/2010, along with navigation buttons for 'Previous', 'Outline View', and 'Next'.

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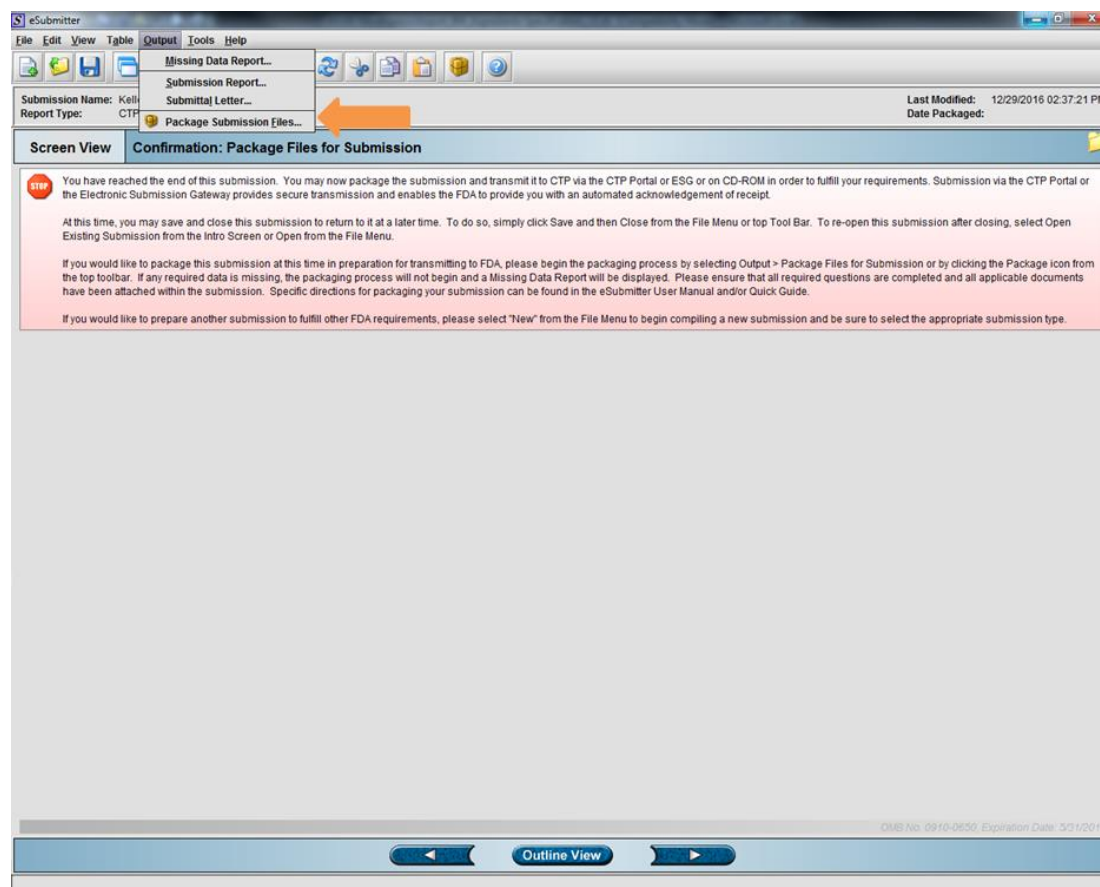
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42) Advance until you get to the confirmation screen.

43) Select the identity of the submitter (if the Authorized Representative, no other information will need to be entered)

44) Advance until a pop up comes up that says “You have reached the end of the Submission form”. At that point, select the “Output” menu and choose “Package Submission files” (as indicated by the orange arrow in the image below)



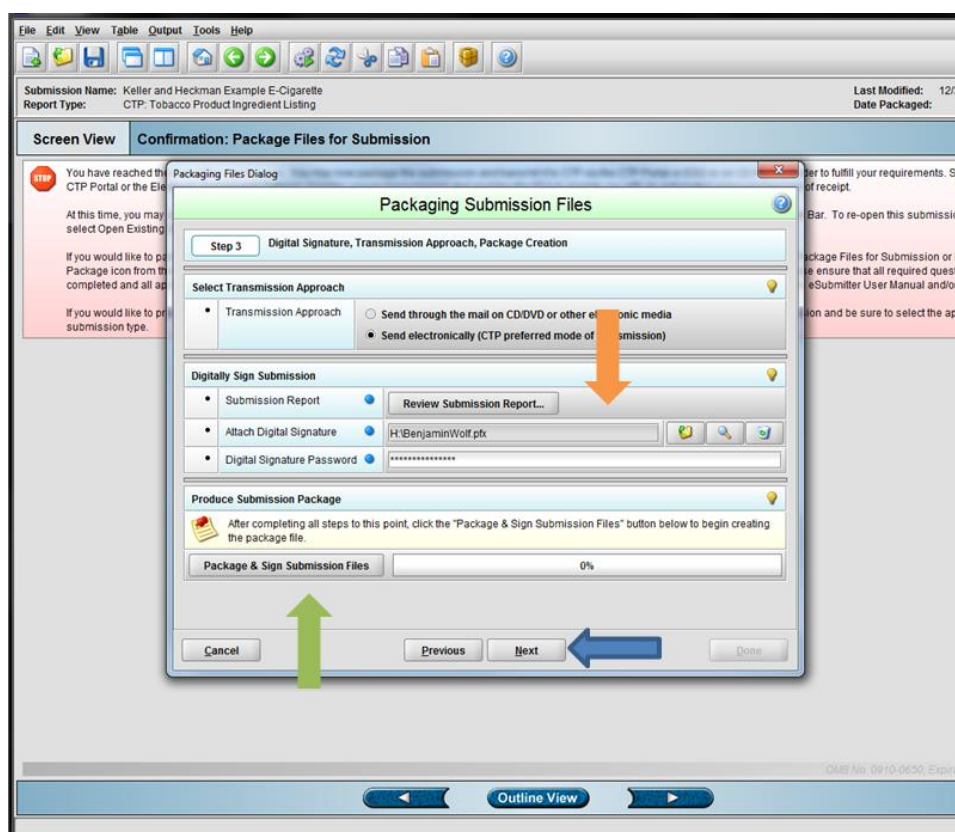
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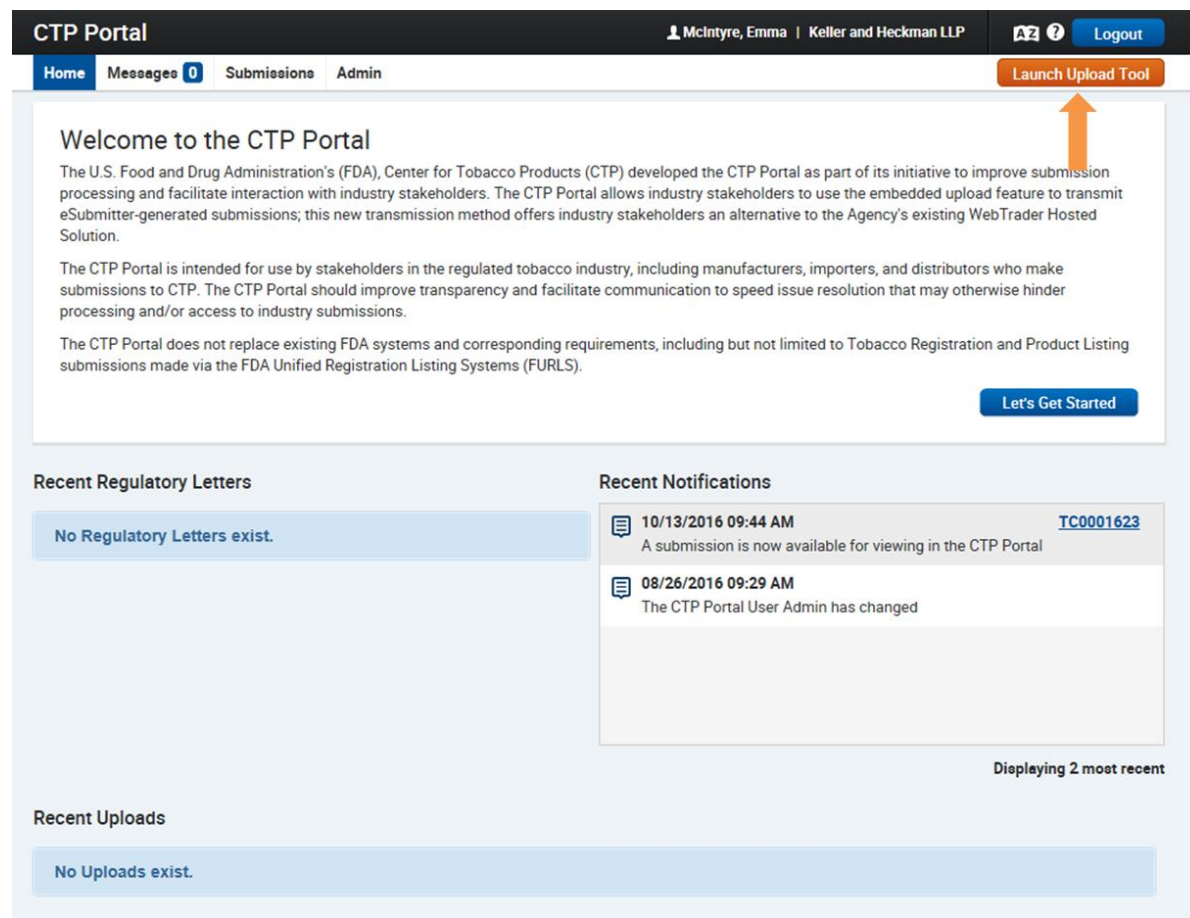
- 45) Once the pop-up for packaging submission files comes up enter the file name and select a location and, if relevant, confirm that the appropriate files have been attached. Finally attach your digital signature (indicated by the orange arrow in the image below), click the “Package and Sign Submission Files” (indicated by the green arrow in the image below) and then click Next (indicated by the blue arrow in the image below)



- 46) You now have a file ready for submission

8. Submitting using the CTP Portal

- 1) From within the CTP Portal, click the “Launch Upload Tool” button (see orange button in the upper right corner of image below)



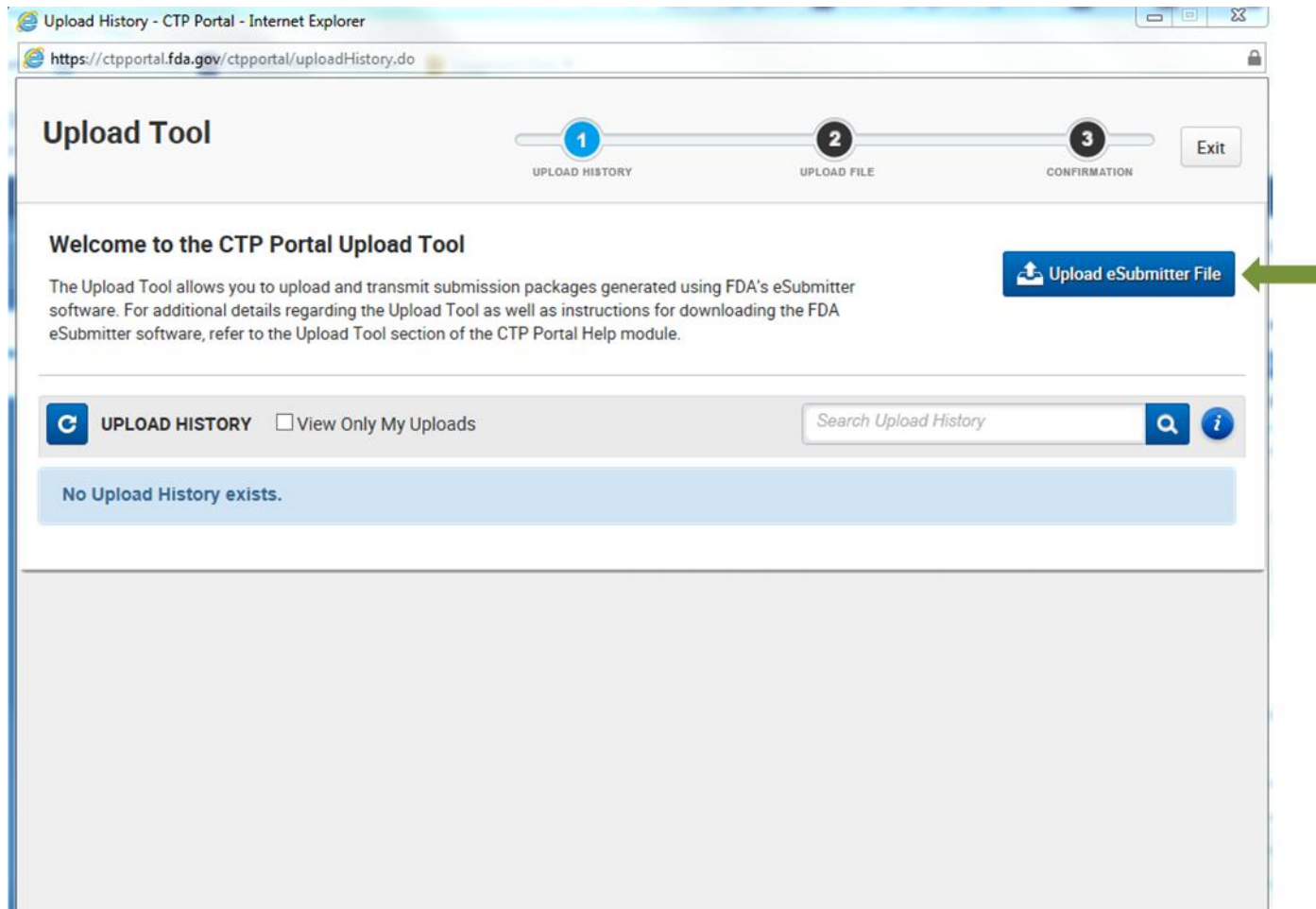
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- 2) Click the blue “Upload eSubmitter File” button (right side of screen, indicated by a green arrow in the image below)



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- 3) After you press the blue “Upload eSubmitter File” button, you will be prompted to browse your computer for the eSubmitter file. Then, you will need to enter a “Package Description” for the submission. The text entered into this field will be displayed in the CTP Portal. Lastly, check the certification box and press the “Upload” button. Follow any additional prompts and you should be sent to a submission confirmation screen

The screenshot shows the 'Upload Tool' interface in a web browser. The browser's address bar displays 'https://ctpportal.fda.gov/ctpportal/uploadFile.do'. The page has a progress bar at the top with three steps: 1. UPLOAD HISTORY, 2. UPLOAD FILE (currently active), and 3. CONFIRMATION. An 'Exit' button is located to the right of the progress bar. The main content area is titled 'Upload File' and contains the following text: 'Use the "Browse" button to locate the zip file you wish to upload. The CTP Portal only allows eSubmitter zip files to be uploaded and only one file can be uploaded at a time. Please refer to the Help/FAQ content provided in the CTP Portal for details.' Below this, it says 'To download eSubmitter: www.fda.gov/forindustry/fdaesubmitter.' There are two required fields: '* File Name' with a text input and a 'Browse' button, and '* Package Description' with a text input and an information icon. Below the 'Package Description' field, it says 'Limited to 150 characters. 0 of (150)'. There is a checkbox for certification: '☐ I hereby certify that the information provided herein is true and that I am authorized to upload a submission with the FDA.' At the bottom left are 'Cancel' and 'Upload' buttons. A large gray area on the right side of the page features a faint upward-pointing arrow icon.

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Exhibits List

- Exhibit 1** eSubmitter Quick Guide
- Exhibit 2** eSubmitter Submissions for CTP
- Exhibit 3** eSubmission User Manual