

HOW TO: **Collect Information Required For The FDA's E-Liquid and E-Vapor Device Ingredient Listing Reports**

This guide outlines the information we believe manufacturers of e-liquids and e-vapor hardware products should collect in order to comply with the FDA's ingredient listing requirements for "deemed" tobacco products. Deemed tobacco products now include: e-liquids, e-vapor devices, and their component parts. We also provide guidance on how to efficiently enter the information into FDA's eSubmitter tool.

For a complete step-by-step guide on using the eSubmitter tool, complete with Microsoft Excel templates, visit vapementors.com/FDA2017-Resources, where you'll find:

- A completed Microsoft Excel template for listing product information
- A step-by-step, in-depth guide for submitting your product information to the FDA and the Center for Tobacco Product (CTP).

[Get all the resources you need remain compliant here >>>](#)

Be advised: Large-scale manufacturers have until August 8, 2017 to submit these forms. Small-scale manufacturers have until February 8, 2018.

A small-scale manufacturer is categorized as having fewer than 150 full-time employees and annual revenues of \$5 million or less.

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FDA has primarily provided three sources of information on how to submit ingredient listings:
the:

1. FDA Guidance for Industry: Listing of Ingredients in Tobacco Products (available at: <http://r20.rs6.net/tn.jsp?t=8a5yinzab.0.0.hyme95pab.0&id=preview&r=3&p=http%3A%2F%2Fwww.fda.gov%2Fdownloads%2FTobaccoProducts%2FLabeling%2FRulesRegulationsGuidance%2FUUCM527044.pdf>). See our summary here: <http://www.kellerheckman.com/FDAs-Ingredient-Listing-Deadline-Rapidly-Approaching-for-Manufacturers-of-E-Vapor-E-Liquid-and-Other-Deemed-Tobacco-Products>.
2. FDA's Form 3742 for available at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM192153.pdf>, and
3. The eSubmitter software templates, which may be uploaded through the CTP Portal.

Because none of these provides instructions for how to complete ingredient reports for vaping devices, *i.e.*, Electronic Nicotine Delivery Systems (ENDS), this document will focus on providing more specific guidelines that we believe will enable industry to complete the ingredient listing for e-vapor devices using **the eSubmitter template** as simply as possible while still meeting FDA requirements. We will highlight where ingredient listing for e-liquid products differs. Some key points to keep in mind:

- 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.**
- 2) The ingredient listing requirement applies to all “finished” products that are intended for sale to consumers, including components and parts of devices. A finished tobacco product is defined in the Deeming Regulation and FDA PMTA guidance as a tobacco product that is sealed in its “final packaging” intended for consumer use (sold directly to consumers). Accordingly, e-liquids, atomizers, coils and control boards that are in their final sealed packaging for sale to consumers are considered “finished” products that must be subject to an ingredient listing. E-liquids and device components and parts that are only sold to other manufacturers (and not to consumers) for “further manufacturing” are not finished products.

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- 3) You will need to submit an ingredient listing for every product that, save for packaging and labeling, is not identical. If the change in packaging could or does result in any change to the product, then the product would still need its own ingredient listing.
- 4) Using eSubmitter, FDA has three designations that it sets for products and ingredients:
 - (a) “products”, (b) “components”, and (c) “ingredients”:
 - a. Products must consist of at least one component
 - b. Components must consist of at least one ingredient
 - c. You should consider limiting the number of components in your product to the fewest that make sense
 - i. For example, when listing a circuit board that is made up of resistors, capacitors, LEDs, transistors, etc. you could list each resistor, capacitor, LED, transistor, etc. as its own component with a single ingredient, or you could list the board as the component and include all of the parts as ingredients. We have found it simpler to designate your product as having a few components made up of many ingredients.
- 5) Information you will need to gather to fill in to eSubmitter includes:
 - Company Name;
 - Company Headquarters D&B DUNS Number (optional);
 - Company Headquarters FDA Assigned Facility Establishment Identification (FEI) Number (optional; this does not yet apply to foreign manufacturing facilities);
 - Company Mailing Address;
 - Authorized Representative’s information (name and mailing address; optional: title, email address, phone number and fax number);
 - US Agent Contact information (for US based companies this can be the Authorized Representative or the same information as Authorized Representative is needed);
 - Unique brand/sub-brand information and SKUs (or equivalent) for each device or component. If there are any other factors that would cause you to use a different SKU (such internet only packaging or for different distributors or labels) you will need that information as well.
 - Use of the product (for consumer, for further manufacturing, or both). As noted above, you do not need to list ingredients if only for further manufacturing. If you only sell to consumers put “Consumer Use”; if the product is sold both to consumer and for further manufacturing, put “Consumer Use and Further Manufacturing Use”
 - Is the product copackaged – “No” unless it is sold with other tobacco products that would also have separate ingredient listings
 - Product Category and Subcategory – for e-liquids and e-vapor devices choose “Electronic Nicotine Delivery System (ENDS)” and then the appropriate subcategory (“Closed” or “Open” “E-Cigarette” or “E-Liquid” or “ENDS Component”)
 - Subbrands that are equivalent but for variations in package size/package/labeling (i.e. on ml-by-ml basis the e-liquids are the same or unit-

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by-unit basis the vaping devices are the same from one product to the next). This might be the case where the same product is sold under different name brands or there are different volumes of e-liquid or multipacks of e-vapor devices (assuming no effects of packaging on the product)

- Product Components
 - Component Type – Choose between: E-Liquid, Atomizer, Coil/Coil Heads, Mouthpiece, Tank/Cartridge, Wick, Other
 - Component Name – there is very little guidance on this. You might be able to simply re-enter the product name or even a generic name like “Complete Vaping Device”
 - If you assemble different components to make a whole product, each thing you assemble might be a component
 - One point to consider is whether you are assembling components that fall cleanly into the categories FDA has laid out
 - Component Manufacturer Name and Unique Identifying Number - depending on how you choose to enter the component name, this might be your company’s information. Regardless, it should be the name of the manufacturer and that manufacturer’s order number.
- Ingredient list for each unique product or component of the product
 - You will need to provide the weight per product or per gram of use for each ingredient in the product as a whole
 - That means you will need to provide the weight of, for instance, a flavor per gram of e-liquid or a coil
 - Do not forget to include ingredients added as processing aids and expected to be removed prior to completion of manufacturing
 - Even if a processing aid is expected to be completely removed during processing, it still must be listed
- For all ingredients include: Ingredient Name, Ingredient Number (your internal designation for the ingredient) and ingredient type (“Single Chemical Substance”, “Leaf Tobacco”, “Complex Purchased Ingredient”). **Note that for e-liquids, our view is that most components will be single chemical entities or complex ingredients. For e-vapor devices, our view is that most components will be considered complex ingredients.**
- For Single Chemical Substances (e.g., nicotine), you need to provide the following information:
 - Unique Scientific Name
 - Type of Name
 - Registry Code (i.e. CAS number)
 - Type of Code (i.e. CAS)
 - Is the ingredient a Reaction Product? If yes, all ingredients known or intended to form this product

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- Tobacco Leaf – this should not be an issue for an e-liquid or e-vapor device manufacturer.
- For each single chemical entity and complex purchased ingredient, you need to provide:
 - Complete manufacturer (supplier) name (or names)
 - Whether the ingredient is made to your specifications
 - If so, FDA requires that you identify which ingredients are made to your specifications.
 - You can submit your ingredient listing to FDA at this time without providing other specifications (aside from ingredients). 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.
 - You will not be able to package your submission without listing the ingredients
 - We believe that you can list an ingredient as its own specified ingredient (see example in “General eSubmitter Instructions”, below)
 - If you choose to list all specified ingredients that are part of a custom complex purchased ingredient, 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
 - Manufacturer ingredient number (like catalog number; how you would communicate to the manufacturer which product you want)
 - The purity measure/metric you use for the ingredient (i.e. degrees brix or specific density) and your acceptance level
 - For a device or device component, you may have to identify some measure that you use to accept the product/component from a vendor
 - The function(s) for each ingredient
 - There are likely to be functions for your e-liquid ingredient within the list
 - Some to consider: Emulsifier, Flavor, Humectant, Moisturizer, Nicotine Source, Solvent, Sweetener
 - Very few of the pre-entered functions are relevant to devices
 - Coils may conduct heat, for example.
 - If a function is not contained in the list, select “Other” and give a very brief description
 - An ingredient may serve more than one function, if so, select or provide all that apply
 - The complete list of functions is:

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- Addictiveness enhancer (including nicotine addictiveness enhancer such as an agent that affects the dosing, perception or action of nicotine)
- Adhesive
- Aerosol Forming Agent
- Anti-Foaming Agent
- Anti-Plasticizer
- Anti-Sticking Agent
- Antioxidant
- Binder
- Biocide
- Carrier
- Casing
- Chemo-sensory agent that affects perception of mainstream or sidestream smoke including smoke color modifiers, smoke odor modifiers and smoke enhancers)
- Coating Agent
- Color
- Combustion Modifier
- Dispersant
- Drying Agent
- Emulsifier
- Fermentation Agent
- Fiber
- Filler
- Film-Forming Agent
- Filtration
- Flavor
- Fuel for Heat Source
- Heat Conductor
- Heat Insulator
- Humectant
- Ink
- Lip Release Agent
- Menthol Delivery
- Moisture Barrier
- Moisturizer
- Nicotine Source
- Oxygen Barrier
- pH Adjuster
- pH Buffer
- Plasticizer

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- Porosity Control Agent
 - Preservative
 - Processing Aid
 - Reduced Ignition Propensity
 - Sizing Agent
 - Solvent
 - Surfactant
 - Sweetener
 - Texture Control Agent
 - Whitener
 - Wrapper
 - Other
 - The method of determining the amount of ingredient added (calculated, tested, or to achieve an outcome (like getting into a pH range))
 - If amount calculated, the singular quantity calculated will suffice
 - If amount tested, you will need the mean quantity and measures of variability
 - If amount to achieve an outcome, you will need the type of target outcome, units of the outcome (i.e. pH), and value of the outcome as well as the typical quantity or range of the ingredient used to achieve that outcome)
 - If there are any processing aids used, you will need to report residuals to FDA
- 6) 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
- 7) For our example, we are providing an ingredient listing for a made up e-cigarette (“Keller E-Cigarette100”) which is solely comprised of a coil head assembly and mouthpiece. In real life there are other parts/components that would need to be listed, but these two components serve as a good example.
- a. The coil head assembly has four “ingredients” each of which are off-the-shelf complex purchased ingredients
 - b. The mouthpiece is a single complex purchased ingredient, but it is made to our specifications from wood and a resin epoxy
 - c. See **Exhibits A, B, and C** for the three completed spreadsheets used to import information about the product and each of the two components. **Electronic copies of Exhibits A, B, and C are currently available online on Keller and Heckman’s website extranet.**

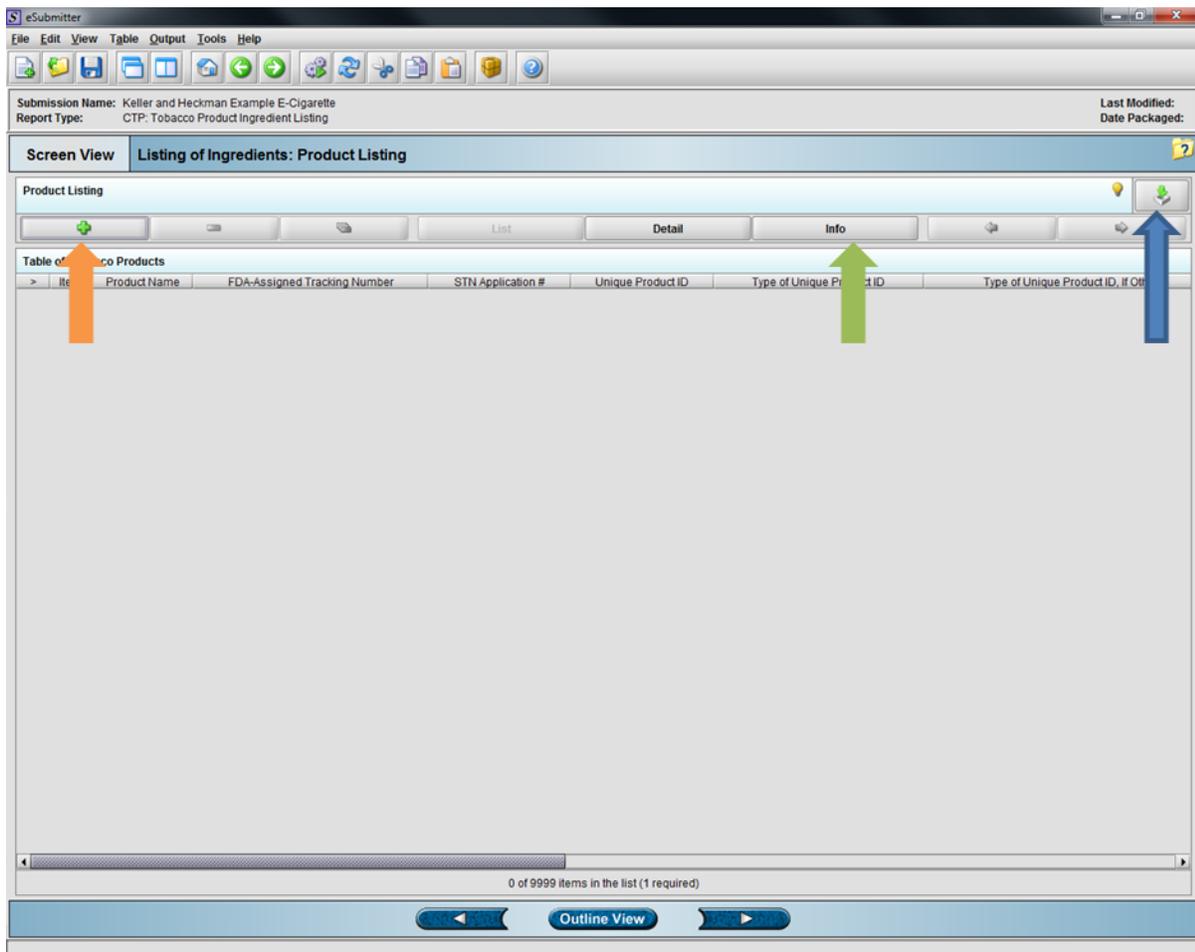
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Note that the specified ingredients for the mouthpiece are not listed in the ingredient list.

General eSubmitter Instructions:

- 1) After entering company/contact information you will advance to the page for entry of product information
 - a. On this page, you can use the spreadsheet to import the complete product list (using the icon indicated by the blue arrow) or hand enter products (using the green plus icon indicated by the orange arrow)



Note that the Info button will give you a link to download the product listing import template

- 2) After importing/entering the products you will have to hand enter the components
 - a. Component entry is on a product-by-product basis
 - b. Make sure you have selected the appropriate product
 - c. Make sure you enter all manufacturers of components and manufacturer part number

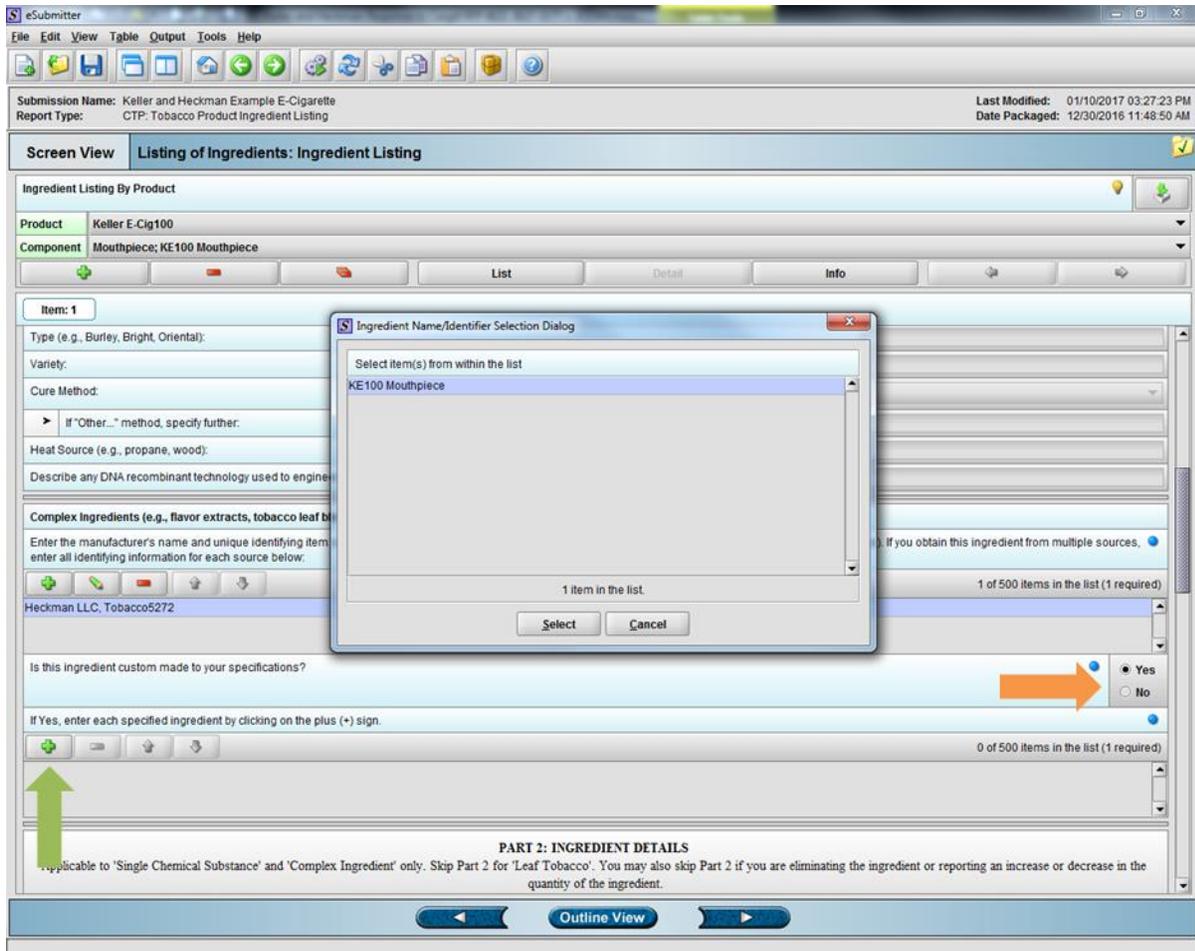
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- d. Considerations for component designation is whether the grouping aligns with FDA's designations (i.e. coil/coil head) and what you actually assemble
 - i. i.e. while FDA might prefer that you list a coil head and wick as separate components, it might make sense to label a purchased assembly containing a coil head and wick as a single component
 - e. For e-liquids, you should be safe listing the entire product as its own component
 - i. i.e. if you have an e-liquid: "60 ml Flavor X, 2.5 mg nicotine" (that is "Flavor X" in size 60 ml with 2.5 mg nicotine, you could list "60 ml Flavor X, 2.5 mg nicotine" as the component.
- 3) After entering components you will be able to upload/enter ingredients for each component in much the same way you entered products
- a. Make sure you have selected the appropriate component for each ingredient import/entry
 - b. Each component should have its own import spreadsheet
 - c. Remember, complex purchased ingredients made to your specifications will need to have the specified sub-ingredients, if any, in the ingredient separately listed. However, we believe that you may meet the requirement by listing as the only specified ingredient the complex purchased ingredient itself (see image below, listing the ingredient KE100 Mouthpiece as the specified ingredient for itself; also note the checkbox for identifying that the ingredient is made to your specifications – indicated by the orange arrow, and the green plus that must be clicked to link the specified ingredients – indicated by the green arrow)



FDA may request additional information in the future if you do not list all specified ingredients as part of a custom complex purchased ingredient. 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. 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

- 4) After entering/importing all ingredients (and specified ingredients as appropriate) for all components, you will have an opportunity to link all equivalent products
 - a. A product is only equivalent if, on a ml-by-ml basis for e-liquids or device-by-device basis for e-vapor devices, they are the same. That means that changes in packaging or labeling that do not impact the identity of the product can be listed here. If the change in packaging material or configuration or the labeling does or

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could result in a change in the identity of the product (i.e. because of different types or amounts of leached materials or changes in oxidative reactions due to changes in surface area to volume ratios) then the product will need to have its ingredients listed separately

- b. Note, manufacturers who must register their establishments and list their products (currently US only) must still list all products, even if differences are in packaging or labeling only. The obligation to list ingredients is separate from the obligation to list products.

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Exhibits List

- Exhibit A** Completed Microsoft Excel Spreadsheet Used to Import KE100 Product Information

- Exhibit B** Completed Microsoft Excel Spreadsheet Used to Import KE100 Mouthpiece Ingredient Information

- Exhibit C** Completed Microsoft Excel Spreadsheet Used to Import KE100 3ohm Coil Ingredient Information