

Domestic Manufacturer Registration and Product Listings Who? What? When? Where? How?



On **Monday, December 5, 2016**, VTA will be hosting a webinar that will be conducted by two FDA attorneys from Kleinfeld, Kaplan & Becker, LLP
Stacy Ehrlich & Will Woodlee



Ms. Ehrlich's and Mr. Woodlee's practices focus on counseling and advocating on behalf of food, dietary supplement, cosmetic, pharmaceutical, medical device, tobacco, and consumer product companies on regulatory and advertising law matters. KKB has been involved in FDA's regulation of tobacco products since early in the legislative process of the Family Smoking Prevention and Tobacco Control Act.

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**JOIN US FOR A WEBINAR ON FDA DEEMING COMPLIANCE
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- WHAT:** *Domestic Manufacturer Registration and Product Listings*
- WHEN:** December 5, 2016 – 3:00 p.m. (eastern) / 2:00 p.m. (central) / 12:00 p.m. (pacific)
- WEBINAR:** Log in to <https://join.freeconferencecall.com/vaportechnology> to watch, listen & ask Qs
- PHONE:** Dial (U.S.): (712) 770-4035, Code: 847262 to listen only
- NOTE:** Please log in (or dial in) early so that we may start the webinar on time
- QUESTIONS:** Email Tony Abboud at: abboud@vaportechnology.org

WHO REGISTERS AND SUBMITS PRODUCT LISTINGS?

DO I NEED TO REGISTER WITH FDA AS AN ESTABLISHMENT BY DECEMBER 31, 2016?

To answer this question, please ask yourself the following:

1. Do I own or operate an establishment located in the United States?
 - If no, you do NOT need to register.
 - FOREIGN MANUFACTURERS SHOULD NOT REGISTER THEIR ESTABLISHMENTS WITH FDA.
 - If yes, go to the next question.
2. In my U.S. facility, do I manufacture finished tobacco products or do I package/label (or repackage/relabel) finished tobacco products?
 - A *finished tobacco product* is a tobacco product, including all components and parts, sealed in final packaging intended for consumer use.
 - A finished product does not include a tobacco product sold or distributed solely for further manufacturing, including those that are labeled or packaged at another facility for consumer use.
 - If no, you do NOT need to register.
 - IMPORTERS AND RETAILERS WHO DO NOT ENGAGE IN ANY MANUFACTURING, LABELING OR PACKAGING IN THE U.S., BUT WHO MERELY MOVE FINISHED PRODUCT IN COMMERCE, SHOULD NOT REGISTER THEIR ESTABLISHMENTS WITH FDA.
 - If yes, you must register the establishment with FDA by December 31, 2016, and list all finished tobacco products manufactured at that establishment (CONTINUE TO NEXT SECTION).

The following information is being provided for general educational purposes only, and is neither intended nor should be construed as legal advice with respect to the Deeming Regulation. Companies affected by the Deeming Regulation should retain able counsel to advise them with respect to compliance. To learn more about the Vapor Technology Association check us out at

www.vaportechnology.org and www.SaveVapor.org

WHAT PRODUCTS MUST BE LISTED?

WHAT ARE THE PRODUCTS THAT I NEED TO LIST WITH FDA BY DECEMBER 31, 2016?

- You must list all finished products manufactured, packaged, or labeled at the registered establishment as of December 31, 2016.
 - A finished product does not include a tobacco product sold or distributed solely for further manufacturing, including those that are labeled or packaged at another facility for consumer use.
- You must also list components or parts manufactured, packaged, or labeled at the establishment if they are distributed from the establishment in final packaging intended for consumer sale.
 - A component or part includes any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product.
- Examples of components or parts could include cartomizers and atomizers.

IMPORTANT DO NOTS

Given the scope of the current legal requirements and FDA's stated enforcement policies:

- **We do not recommend that any company voluntarily register and submit a product listing for any foreign manufacturing establishment.**
- **We do not recommend that any importer that does not engage in manufacturing activities voluntarily register and submit a listing of products distributed from the importer's domestic warehouse.**
- **We do not recommend including in the product listing for any domestic manufacturing establishment any imported or other finished product that does not undergo any manufacturing step there or any product intended solely for further manufacturing (including packaging or labeling) at another facility.**

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HOW DO I REGISTER?

HOW DO I REGISTER MY ESTABLISHMENT AND LIST MY PRODUCTS BY DECEMBER 31, 2016?

- An owner or operator may register and submit a product listing electronically using the [FURLS](#) system or using the paper form [3741a](#). You may access FDA's revised guidance on compliance with the registration and listing requirements by clicking [here](#).
- You may find instructions and video tutorials on using FDA's electronic FURLS system on FDA's website by clicking [here](#).
- If you would like to file electronically, we strongly recommend that you set up your FURLS account **as soon as possible**. Industry members have reported, and FDA has acknowledged, ongoing FURLS functionality issues, and the FURLS helpdesk staff has not always responded promptly to industry requests and questions.
- FDA has made available on its website examples of completed registration and listing forms for [E-Liquid](#) and [ENDS](#) products. Click on the links to redirect you to the FDA's exemplars.
- You do NOT need to include consumer information and a representative sampling of all other advertising in conjunction with product listings for vapor products/devices or e-liquids.
- For each product included in the listing, you will need to include copies of all labeling for that product; labeling includes all labels and other written, printed, or graphic matter on the product, on any of its wrappers or containers, or otherwise accompanying the product when distributed.

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