VTA
VAPOR TECHNOLOGY ASSOCIATION

VTA GUIDANCE UPDATE

September 19, 2017

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

On **Monday, December 5, 2016**, VTA hosted a webinar 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

In this Guidance

INTREPID

WEBINAR ON FDA DEEMING COMPLIANCE SPONSORED BY INTREPID BRANDS AND VAPOR BEAST

VAPOR BEAST

WHAT: ***Domestic Manufacturer Registration and Product Listings***

WHEN: December 5, 2016 / First Update: September 1, 2017 / 2nd Update: September 19, 2017

WEBINAR: Listen to a recording of the webinar here: **https://youtu.be/l7jDW7ZGUmA**

QUESTIONS: **info@vaportechnology.org**

UPDATE 1: The DEADLINE for Company Registration and Product Listing is NOW **September 30, 2017**
UPDATE 2: **FDA permits "group" label submissions for products with substantially identical labels.**

WHO REGISTERS AND SUBMITS PRODUCT LISTINGS?

DO I NEED TO REGISTER WITH FDA AS AN ESTABLISHMENT BY SEPTEMBER 30, 2017?

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 September 30, 2017, and list all finished tobacco products manufactured at that establishment (CONTINUE TO NEXT SECTION).

WHAT PRODUCTS MUST BE LISTED?

WHAT ARE THE PRODUCTS THAT I NEED TO LIST WITH FDA BY SEPTEMBER 30, 2017?

- You must list all finished products manufactured, packaged, or labeled at the registered establishment as of **SEPTEMBER 30, 2017**.
  - 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.**

HOW DO I REGISTER?

HOW DO I REGISTER MY ESTABLISHMENT AND LIST MY PRODUCTS BY *SEPTEMBER 30, 2017*?

- 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.

- 9/19/2017 UPDATE: Alternatively, FDA has stated that where you have a line of products with labeling that is essentially identical (e.g., the same formatting, fonts, colors, background text, and images), you may submit information that represents the labeling for that line of products. FDA has provided an example of how you could submit information that represents the labeling for a selected line of products using a "package label plan" that includes a "model label" and a "product variation index." You can read the whole guidance and Appendix A by clicking here: September 15, 2017, revised FDA guidance on registration and listing.

  For your convenience, a copy of the FDA's "Appendix A – Example Package Label Plan" in the new guidance is below.

APPENDIX A –EXAMPLE PACKAGE LABEL PLAN

Note: Appendix A is intended to serve as one example of a circumstance in which FDA does not intend to enforce the requirements in subsections 905(i)(1)(A) and (B) with regard to labeling submissions. It describes a "package label plan," which could be submitted by a registrant to represent the labeling for a selected line of products. FDA may exercise enforcement discretion in other circumstances as described in the guidance.

In this example, a package label plan consists of two parts submitted together, a "model label" and a "product variation index."

The model label contains a proxy, such as placeholder text, for the variations in the label, such as variations in package size, nicotine strength, PG/VG ratio, and flavor. The proxy, such as placeholder text, is the same size, font, and color as it will appear on the actual label for the individual product. All formatting, fonts, colors, background text, and images are represented on the model label as they will appear on the actual label.

The product variation index is a listing of all variations for a specific tobacco product; limited to variations in package size, nicotine strength, PG/VG ratio, and flavor. A product variation index lists all combinations of the variations that will be using the model label. Each tobacco product listing on the index corresponds with the attached model label. The product variation index indicates the corresponding model label and also includes product name and product identification number columns.

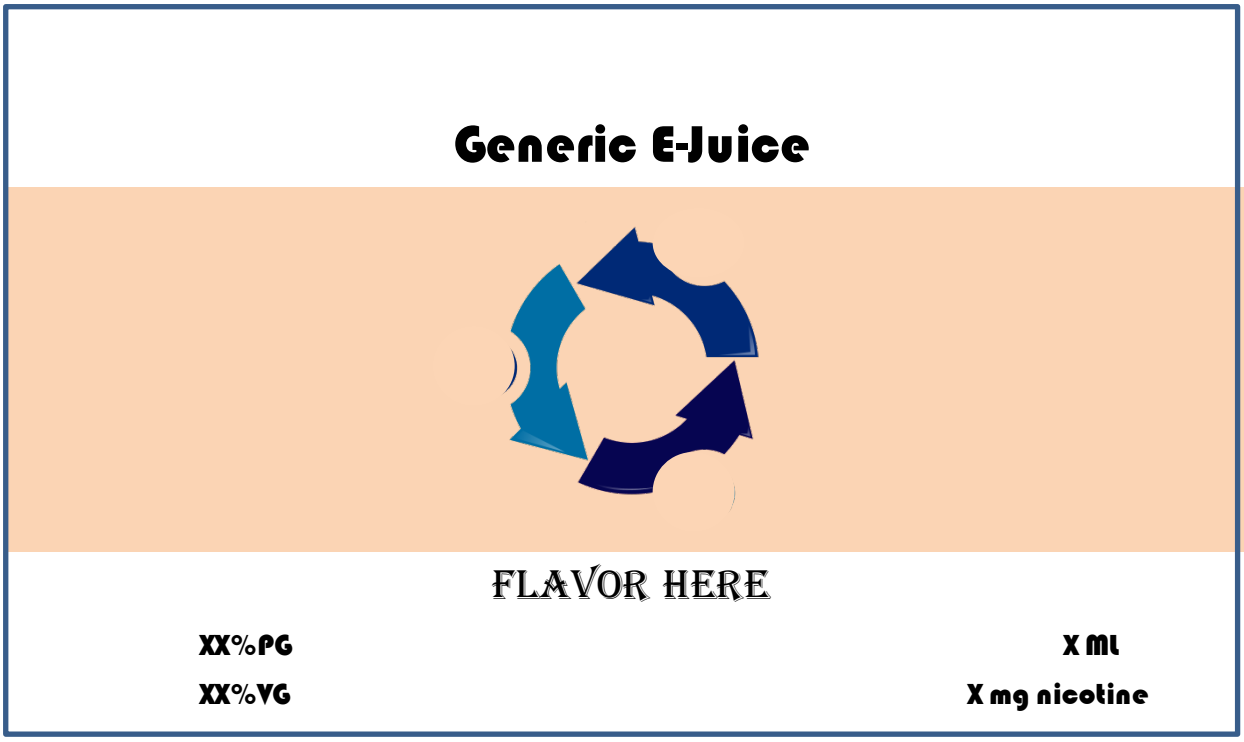
The package label plan would be uploaded to the electronic submission portal, as discussed in Section IV.D of the guidance, and be associated with all product listings represented in the variation index. For the products using a particular package label plan, the registrant would upload one file and that file would be associated with the relevant product listings by selecting those listings. Associating a label submission with a product that does not use that label or is not covered by that package label plan would not fall within the above stated compliance policy.

Upon reviewing the package label plan, if FDA determined that it needed additional labeling submissions, it would notify the firm that the submission of additional labeling is needed. In addition, the package labeling must comply with all other applicable labeling requirements under the FD&C Act and implementing regulations.

The examples below are for 'Generic E-Juice' an e-liquid product, which comes in three package sizes, three different nicotine strengths, including a zero nicotine formula, two variations of PG/VG ratio, and three flavors.

Example A:

I. Sample



Note: In the above model label, the proxy for package size, nicotine strength, PG/VG ratio and flavor are all being represented by placeholder text. Here, the variable elements are represented by X's and the text 'Flavor Here'.

Formatting, fonts, colors, background text, and images, and any other elements except package size, nicotine strength, PG/VG ratio, and flavor should remain identical across labels for all products listed under this package label plan. All proxies, including placeholder text, should be represented in the font, size, and color in which they will appear on the actual label.

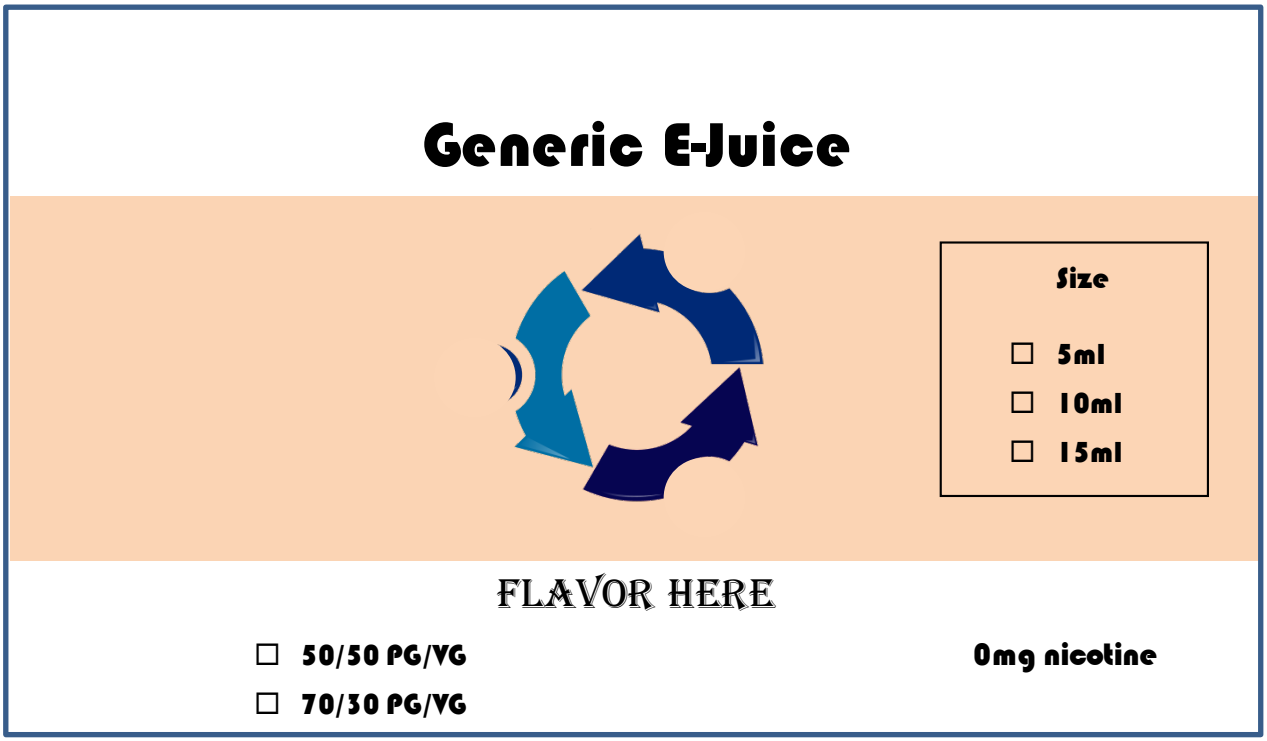
II. Product Variation Index

Product Name	Product Identification Number	Size	Nicotine Strength	PG/VG Ratio	Flavor
Generic E-Juice	G001	5ml	3mg	50%PG/50%VG	A
Generic E-Juice	G002	5ml	3mg	50%PG/50%VG	B
Generic E-Juice	G003	5ml	3mg	50%PG/50%VG	C

Generic E-Juice	G004	5ml	3mg	70%PG/30%VG	A
Generic E-Juice	G005	5ml	3mg	70%PG/30%VG	B
Generic E-Juice	G006	5ml	3mg	70%PG/30%VG	C
Generic E-Juice	G007	5ml	6mg	50%PG/50%VG	A
Generic E-Juice	G008	5ml	6mg	50%PG/50%VG	B
Generic E-Juice	G009	5ml	6mg	50%PG/50%VG	C
Generic E-Juice	G010	5ml	6mg	70%PG/30%VG	A
Generic E-Juice	G011	5ml	6mg	70%PG/30%VG	B
Generic E-Juice	G012	5ml	6mg	70%PG/30%VG	C
Generic E-Juice	G013	10ml	3mg	50%PG/50%VG	A
Generic E-Juice	G014	10ml	3mg	50%PG/50%VG	B
Generic E-Juice	G015	10ml	3mg	50%PG/50%VG	C
Generic E-Juice	G016	10ml	3mg	70%PG/30%VG	A
Generic E-Juice	G017	10ml	3mg	70%PG/30%VG	B
Generic E-Juice	G018	10ml	3mg	70%PG/30%VG	C
Generic E-Juice	G019	10ml	6mg	50%PG/50%VG	A
Generic E-Juice	G020	10ml	6mg	50%PG/50%VG	B
Generic E-Juice	G021	10ml	6mg	50%PG/50%VG	C
Generic E-Juice	G022	10ml	6mg	70%PG/30%VG	A
Generic E-Juice	G023	10ml	6mg	70%PG/30%VG	B
Generic E-Juice	G024	10ml	6mg	70%PG/30%VG	C
Generic E-Juice	G025	15ml	3mg	50%PG/50%VG	A
Generic E-Juice	G026	15ml	3mg	50%PG/50%VG	B
Generic E-Juice	G027	15ml	3mg	50%PG/50%VG	C
Generic E-Juice	G028	15ml	3mg	70%PG/30%VG	A
Generic E-Juice	G029	15ml	3mg	70%PG/30%VG	B
Generic E-Juice	G030	15ml	3mg	70%PG/30%VG	C
Generic E-Juice	G031	15ml	6mg	50%PG/50%VG	A
Generic E-Juice	G032	15ml	6mg	50%PG/50%VG	B
Generic E-Juice	G033	15ml	6mg	50%PG/50%VG	C
Generic E-Juice	G034	15ml	6mg	70%PG/30%VG	A
Generic E-Juice	G035	15ml	6mg	70%PG/30%VG	B
Generic E-Juice	G036	15ml	6mg	70%PG/30%VG	C

Example B:

I. Sample



Note: In the above model label for the zero nicotine formulation, the proxy for size and PG/VG ratio are represented with unmarked checkboxes and the flavor is indicated with the placeholder text "Flavor Here."

Formatting, fonts, colors, background text, and images, and any other elements except package size, PG/VG ratio, and flavor, should remain identical across labels for all products listed under this package label plan. All proxies, including placeholder text, should be represented in the font, size, and color in which they will appear on the actual label.

II. Product Variation Index

Product Name	Product Identification Number	Size	Nicotine Strength	PG/VG Ratio	Flavor
Generic E-Juice	G037	5ml	0mg	50%PG/50%VG	A
Generic E-Juice	G038	5ml	0mg	50%PG/50%VG	B

Generic E-Juice	G039	5ml	0mg	50%PG/50%VG	C
Generic E-Juice	G040	5ml	0mg	70%PG/30%VG	A
Generic E-Juice	G041	5ml	0mg	70%PG/30%VG	B
Generic E-Juice	G042	5ml	0mg	70%PG/30%VG	C
Generic E-Juice	G043	10ml	0mg	50%PG/50%VG	A
Generic E-Juice	G044	10ml	0mg	50%PG/50%VG	B
Generic E-Juice	G045	10ml	0mg	50%PG/50%VG	C
Generic E-Juice	G046	10ml	0mg	70%PG/30%VG	A
Generic E-Juice	G047	10ml	0mg	70%PG/30%VG	B
Generic E-Juice	G048	10ml	0mg	70%PG/30%VG	C
Generic E-Juice	G049	15ml	0mg	50%PG/50%VG	A
Generic E-Juice	G050	15ml	0mg	50%PG/50%VG	B
Generic E-Juice	G051	15ml	0mg	50%PG/50%VG	C
Generic E-Juice	G052	15ml	0mg	70%PG/30%VG	A
Generic E-Juice	G053	15ml	0mg	70%PG/30%VG	B
Generic E-Juice	G054	15ml	0mg	70%PG/30%VG	C