THE
NATIONAL LAW REVIEW

New FDA Guidance Document on Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments Published

Tuesday, September 19, 2017

Just two weeks before the September 30, 2017 registration deadline for U.S. tobacco product manufacturing establishments, on Friday, September 15, 2017, the U.S. Food and Drug Administration (FDA) published a Revised Guidance for Industry on *Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments*. See our original post summarizing the registration requirements here.

Article By Benjamin K. Wolf
Azim Chowdhury Keller and Heckman LLP
Publications

Biotech, Food, Drug
All Federal

Has the Deadline Changed?

No. Registrations and product listings are still due by September 30, 2017 for U.S. manufacturing establishments. This applies to deemed tobacco products marketed as of August 8, 2016, the effective date of the Deeming Regulation.

How Do I Register?

FDA strongly encourages electronic submission of establishment registrations and product listings through the FDA Unified Registration and Listing System (FURLS) which can be accessed here. FURLS is only used to register an establishment and submit a product listing. Do not confuse this with the CTP Portal, which you can use to submit other regulatory document (e.g., ingredient reports, health document submissions, etc.) To obtain a FURLS account and to view more instructions and webinars see here. Alternatively, you may file your Establishment Registration manually by filling out and Form FDA 3741a and mailing all of the necessary materials to CTP's Document Control Center.

View FDA's latest Webinar "Using the Tobacco Registration and Listing Module of FURLS - Tips and Recent Enhancements" here (published September 18, 2017).

Who Registers their Establishments and Submits Product Listing Information?

The revised guidance clarifies that owners and operators of **domestic** U.S. establishments engaged in manufacturing regulated tobacco products are required to register and provide a product list to FDA. This requirement does not extend to foreign establishments (e.g., e-vapor device manufacturers in China) or U.S. importers, distributors or retailers who merely distribute and sell products, but are not engaged in any manufacturing activity (e.g., manufacture, preparation, compounding, or processing, including bottling, packaging and labeling). FDA also encourages establishment owners to act as the agent for all operators and to register all establishments it owns and to submit the associated product listing, in order to reduce redundant submissions. If you have any questions about how to best structure your registration and product listing for your particular business, please let us know.

What Products Need to be Listed?

Despite the fact that the Form 3741a and the template FURLS product listing spreadsheet provided by FDA allow

companies to indicate whether a particular product is for "Consumer Use" or "Further Manufacturing", FDA's revised guidance clarifies that the listing requirement only applies to finished tobacco products sealed in final packaging intended for consumers use. This includes components and parts sold directly to consumers in final sealed packaging. For example, an e-liquid sold in a sealed bottle for use by consumers in an open-system device would be a finished tobacco product, but an e-liquid intended to be filled into a closed system cigalike would be for further manufacturing, and should not be listed.

What Information Should be Submitted as Part of Establishment Registration and Product Listing?

Registration Information

The following information is needed to register manufacturing establishments:

- The name and full address of each establishment engaged in manufacturing the registrant owns or operates, as of the date of registration.
- The name and places of business of the owner or operator. In the case of a partnership, include the name of each partner. In the case of a corporation, include the name of each corporate officer and director, and the State of incorporation.

Optional information includes an email address and a Data Universal Numbering System (D-U-N-S) number or other unique identifier (codes) for the place of business of the owner, the place of business of the operator, and the location of the establishment.

Product Listing Information

For the product list, FDA's template product listing spreadsheet (available in FURLS) should be used, particularly if you are processing the registration online through FURLS. The spreadsheet identifies the information that must be submitted for each product, e.g., product identification number (SKU), intended use (consumer use), product category (ENDS), subcategory (e-liquid), open/closed system, flavor, and advertising, labeling and consumer information. Please note that **each** unique product must be identified on your product list including, for example, e-liquids under the same brand or flavor that vary in terms of package (e.g., bottle) size, nicotine strength and/or Propylene Glycol (PG)/Vegetable Glycerin (VG) ratio.

Do I need to submit labels for all my product variations?

In addition, the product listing must include labeling information, but FDA's revised guidance clarifies that e-liquid manufacturers in particular need **not** submit labels for all product variations. Specifically, the guidance states (on page 9):

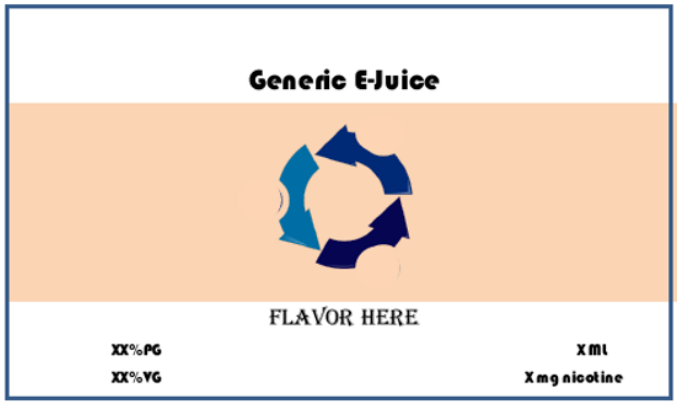
However, FDA recognizes that product listing for some tobacco products may result in numerous labeling submissions that the manufacturer must prepare and submit. For example, variations in package size, nicotine strength, Propylene Glycol (PG)/Vegetable Glycerin (VG) ratio, and flavor can result in thousands of individual product labeling submissions.

In order to reduce the amount of uploaded labeling submissions, FDA does not, at this time, intend to enforce the requirements that owners and operators submit the labeling for each individual listed tobacco product if the registrant submits the information that represents the labeling for a selected line of products. In deciding whether a registrant's submitted information falls within this compliance policy, FDA may consider whether the tobacco products' labeling is essentially identical (e.g., the same formatting, fonts, colors, background text, and images) and whether the variations are limited to package size, nicotine strength, PG/VG ratio, and flavor. However, we recommend that zero nicotine formulas of a product, or product line, be grouped separately from products with nicotine.

Rather, as described in Appendix A to the revised guidance, registrants may submit a separate "package label plan", which is a model/generic product label with placeholder text for the specific variations, along with a "product variation index" which lists all the variations for a specific product, e.g. package size, nicotine strength, PG/VG ratio and flavor. The product variation index must list all combinations of the variations that will be using the model label. The examples from FDA's revised guidance are copied below.

The Package Label Plans, including the Model/Generic Labels and Product Variation Indices can be uploaded in FURLS by creating a single PDF containing the label and the index. Once uploaded into FURLS you will be given the option of associating the file with all applicable products.

Example A - Sample Model Label (Package Label Plan) for nicotine containing products from the revised FDA guidance:



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'.

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	G 005	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	G 010	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	G 015	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	G 020	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	G 025	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	G 030	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	G 035	15ml	6mg	70%PG/30%VG	B
Generic E-Juice	G036	15ml	6mg	70%PG/30%VG	C

Example A - Product Variation Index

Example B - Sample Model Label (Package Label Plan) for 0 mg nicotine products from the revised FDA guidance:

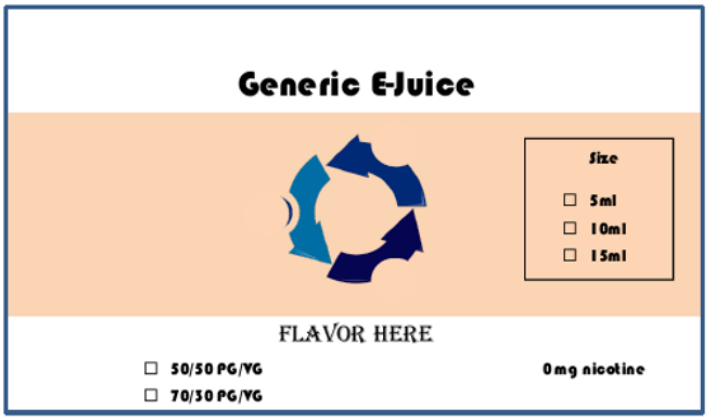
Example B - Product Variation Index

What about advertisements and "consumer information"?

Finally, we note that despite previously implying that this information was optional, FDA's revised guidance states that if product advertising exists, a representative sampling of such advertisements must be provided with the product listing. FDA interprets "a representative sampling of advertisements" to mean typical advertising material that reflects the full range of promotional statements made for the tobacco product. For example, if more than one magazine advertisement is used, but the promotional content is essentially identical, only one need be submitted.

FDA's revised guidance further notes that, in addition, the product listing must include "a copy of all consumer information" to the extent the information is not advertising and has not already been provided as a form of product labeling. Consumer information does not include information directed at wholesalers, distributors or retailers where such information is not available to consumers (e.g., product specifications intended for manufacturing purposes, photos of components or parts not intended for individual sale, or communications between companies), but may include items like consumer brochures.

Source URL:
https://www.natlawreview.com/article/new-fda-guidance-document-registration-and-product-listing-owners-and-operators



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.

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