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FDA's Establishment Registration and Product Listing Deadline is Fast Approaching - Are You Prepared?

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Section 905(b) of the ***Tobacco Control Act*** requires every person who owns or operates any "establishment" in the United States that manufactures, prepares, compounds, or processes a "tobacco product" to register with FDA by December 31 of each year. Now that the Deeming Regulation is effective, e-vapor products, including their components and parts (e.g., e-liquids that contain tobacco-derived nicotine), are considered regulated tobacco products. If you own or operate a facility in the United States that manufactures, prepares, compounds, or processes an e-vapor product, which includes repackaging or otherwise changing the container, wrapper, or labeling of such product package, then you must register with FDA by the end of the year.

At the time of registration, registrants must also submit to FDA a **detailed list of all products** that are being manufactured, prepared, compounded, or processed for commercial distribution, along with copies of consumer information, all product labeling, and a representative sampling of advertisements. Registrants must also file a biannual report of certain changes to their product lists.

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 documents (e.g., ingredient reports, health document submissions, etc.)

Alternatively, you may file your Establishment Registration manually by filling out and Form FDA 3741 and mailing all of the necessary materials to CTP's Document Control Center, or by packaging the files electronically using FDA's eSubmitter software and submitting that package through the CTP Portal.

Establishment Registration

Domestic manufacturers of finished tobacco products must register their facilities.

Deemed tobacco products, including e-liquids, that are intended or reasonably expected to be used with nicotine or tobacco, are now regulated by FDA, and are thus subject to the Establishment Registration and Product Listing requirements of the Tobacco Control Act.

Section 905(b) (21 U.S.C. 387e(b)) of the Act requires that domestic businesses engaged in the preparation, manufacture, compounding, repackaging, relabeling or processing of finished tobacco products register their establishment(s) on or before **December 31** of each year.

In FDA's Registration and Product Listing guidance document, released in July, 2016, FDA states it only intends to enforce the registration and listing requirements with respect to domestic manufacturers of "finished tobacco products." A finished tobacco product is defined as a "tobacco product, including all components and parts, sealed in final packaging intended for consumer use" (and do not include "products that are sold or distributed solely for further manufacturing").

Only Domestic Establishments

Per Section 900(20) (21 U.S.C. 287(20)) of the TCA, a tobacco product manufacturer means "any person, including any repacker or relabeler, (A) who manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." FDA's guidance document states, however, that an importer who does not own or operate "domestic establishments engaged in manufacturing tobacco products" is not subject to the registration and listing requirements. Accordingly, only domestic U.S. establishments engaged in the manufacture, compounding, repackaging, relabeling or processing of finished tobacco products are required to register their facilities and provide product information. This means e-liquid and e-vapor device manufacturers, including vape shops that mix, bottle, assemble or label their own products, located in the United States must register their manufacturing establishments with FDA by the end of the year. As noted, this requirement does **not** currently apply to foreign manufacturing establishments.

Therefore, if you are both a domestic manufacturer and produce finished tobacco products, you must register your U.S. manufacturing facility as directed by FDA by December 31, 2016. Registration instructions are provided below. The information

required by FDA includes:

- The name and address of establishments engaged in manufacturing and owned by the registrant as of the date of registration;
- The name and place of business of the owner or operator; and
- If filing electronically, FDA also recommends providing an email address and DUNS number.

Tobacco products that are produced in an establishment that is not registered under Section 905 will be deemed misbranded per Section 903(a)(6) (21 U.S.C. 387c(a)(6)), which can lead to enforcement actions against the manufacturer such as fines, seizures, or injunctions.

Product Listing

When you register your domestic facility, you must also list the tobacco products you manufacture and provide information regarding those products.

In conjunction with registration, Section 905(i)(1) requires manufacturers to submit a complete list of tobacco products being manufactured for distribution. A manufacturer's tobacco product list must be accompanied by certain product information. At this time, the principal requirement is that the product list must include all labeling for each product, as well as "a representative sampling of advertisements" for each product. FDA's guidance document states that FDA interprets "representative sampling" to mean "typical advertising material that reflects the full range of promotional statements made for the tobacco product." If manufacturer's have additional consumer information that is not submitted as either advertising or labeling, manufactures should submit this consumer information as well. This means that when you register your manufacturing facilities, the list of products produced at such facility must be accompanied by copies of labels and advertising materials (e.g., any ads for your products in VAPE Magazine, for example) for each product.

FDA's Registration and Listing guidance states that "each product included in a product listing [should] be clearly identified and distinguished." If two products are different, for example if they contain different components or parts, the products should be listed separately. FDA requires that the listed products be identified by category, unique name, and identification number such as a SKU or UPC, as needed. For examples of the information required for a product listing, see pages 8 and 9 of FDA's Form 3741.

Finally, under Section 905(i)(3), changes that occur to a manufacturer's most recent product list must be submitted biannually, during June and December. As FDA's guidance explains, these changes include: tobacco products introduced for commercial distribution; tobacco products for which manufacturing was discontinued; tobacco products that for which manufacturing was previously discontinued but which has since resumed; and "any material change" to information previously submitted in a product list.

Examples

FDA's website for manufacturers provides the following **examples of completed registration and listing forms** for various types of tobacco products:

- Electronic Nicotine Delivery Systems (ENDS)
- E-Liquid

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