VTA
VAPOR TECHNOLOGY ASSOCIATION

RETAILER GUIDANCE

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What Retailers Need to Know About the Upcoming Facility Registration & Product Listing Deadline on 9/30/17

VTA has been getting a number of questions from our retailer membership about what the upcoming Facility Registration and Product Listing deadline means to them. Specifically, retailers are asking about whether they should be requesting FDA Establishment Identifier (FEI) numbers and Tobacco Product (TP) numbers from manufacturers by September 30, 2017, and if they don't receive those numbers should retailers stop selling products on October 1, 2017. The short answer to both questions is NO. The following explains why and answers the questions that we have received.

I'm a retailer. Do I have an obligation to make sure that the products I am selling are registered?

No. Retailers do not have an obligation under the Deeming Regulation to make sure that products are registered. You will not incur any penalties for failing to verify.

Should I demand that manufacturers give me the TP numbers for their products that I am selling?

Not really. Asking for TP numbers is of little use to you as a retailer. *First*, the TP number is an internal FDA tracking number and actually may change over time. *Second*, not all products must be registered with the FDA. Imported products do not have an obligation to be registered with the FDA and consequently will not receive a TP number. *Third*, FDA does not assign TP numbers immediately. For those manufacturers who submit their product listing using the paper form it may take FDA a long time to process those listings. So, the TP number has little meaning in the overall regulatory scheme.

Should I demand that manufacturers give me the FEI numbers for their products that I am selling?

Demanding FEI numbers by October 1, 2017, is unrealistic and will be of little assistance to you. Remember, the *deadline* for filing is September 30, 2017. FDA takes time to process the registrations and FEI numbers may not be immediately available on the website. Also, remember that manufacturers can submit their registrations *on paper*. So, we have no idea how long it will take FDA to process those paper registrations and assign FEI numbers.

In other words, it could be weeks or months before manufacturers have FEI numbers for all their products. Also, FEI numbers are only assigned to domestic manufacturing facilities, not to importers or distributors. Foreign manufacturers and importers are not required by law to register. Hence, there may be manufacturing facilities for which FEI numbers are never issued.

Do I have to pull products off the shelves on October 1 if I don't have proof that they are registered?

No. Retailers are not required to police this part of the regulation. It is up to the FDA to determine whether a product should be taken off the market. Until such time as the FDA orders a product removed, retailers have no obligation to remove a product. FDA will issue warning letters to manufacturers and inform retailers about those products that must be pulled off the market for whatever noncompliance reason at least a month in advance.

But, what if I want proof that products I'm selling are registered?

Given all the above, retailers who want assurances that they are selling registered products should ask each manufacturer for products that they are selling to provide them a letter affirming that the manufacturer has complied with the product listing and facility registration requirement and that their products you are selling have been registered with the FDA as of September 30, 2017.

What happens to me if I'm selling a product that is not registered?

Similar to other parts of the Deeming Regulation, if the FDA finds that your shop is selling a product which has not been registered by the manufacturer, they would start by giving *the manufacturer* a warning letter, after which the *manufacturer* will be given time to comply (typically a month) with removing the product. *Retailers will not be issued warning letters* if a product is not registered because registration is a manufacturer's obligation, not a retailer obligation. Nowhere in the FDA guidance does it mention retailers in connection with product listing obligations and/or the September 30 deadline.

What about hardware, parts or liquids from overseas? Do they even need to be registered?

No. Imported products don't need to be registered, so you can't reasonably demand registration information from those manufacturers.

Are retailers required to maintain a list of their inventory's FEI and TP numbers?

No. There is no such requirement on retailers and, more importantly, retailers are not required to police the regulation in this manner.