RegAlert: E-Cigarettes and Deemed Tobacco Products Require FDA Clearance effective August 8, 2016
July 29, 2016

The Food and Drug Administration (FDA) finalized a rule on May 10, 2016 – Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act – which extends the FDA’s authority beyond cigarettes, cigarette tobacco, and smokeless tobacco to include the regulation of electronic nicotine delivery systems (such as e-cigarettes and vape pens), all cigars, hookah (waterpipe) tobacco, pipe tobacco and nicotine gels, among others.

Under staggered timelines, the FDA expects that manufacturers will continue selling their products for up to two years while they submit – and an additional year while the FDA reviews – a new tobacco product application. The FDA will issue an order granting marketing authorization where appropriate; otherwise, the product will face FDA enforcement.

This final rule goes into effect on August 8, 2016. The entire Final Rule is posted below; here are specific highlights:

- Age restriction of 18 years old to receive items covered by this Final Rule
- Items now covered under the Final Rule include E-cigarettes, hookah tobacco, cigars, nicotine gels, and nicotine dissolvables
- All of the impacted tobacco products will require FDA registration and full FDA review and approval
- Future requirements include health warning labels (effective on May 10, 2018)
- Parts and components of tobacco products are included so for E-cigarettes this includes the vaping liquid, atomizers, tank systems, flavors, batteries, etc.
- The Final Rule also details some items that are EXEMPT – spittoons, ashtrays, pipe pouches, hookah tongs, humidors, conventional matches and lighters
The FDA noted this Final Rule extends the scope of the tobacco regulations to cover ALL tobacco products that meet the statutory definition. The FDA said nicotine patches, for example, could be marketed for recreational use. They would then be subject to the tobacco product regulations.

The FDA defines IMPORTER in the context of the tobacco regulations and adds new responsibility. Their regulations now define importer as “any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States”. FDA is amending the tobacco regulations, under General Responsibilities, to specify that manufacturers, distributors, retailers, and IMPORTERS “…are responsible for insuring that the covered tobacco products that they manufacture, label, advertise, package, distribute, IMPORT, sell or hold for sale comply with all applicable requirements”.

**Timeline for Implementation: August 8, 2016**

**References:**

FDA Final Rule:
https://federalregister.gov/a/2016-10685

FDA Guidance Document on Tobacco:
http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm

FDA Fact Sheet on New Tobacco Rule:
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm