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FDA Regulation of E-Cigarettes: The What, When, and Warnings

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On May 10, 2016, the Food and Drug Administration (FDA) issued a final rule extending its regulation of "tobacco products" to include electronic cigarettes and similar products, sometimes called Electronic Nicotine Delivery Systems (ENDS). Specifically, the regulations will apply to vaporizers, vape pens, hookah pens, e-cigarettes, e-pipes, as well as certain components or parts of ENDS. The FDA has defined "components" or "parts" as "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." 21 CFR Parts 1100, 1140 and 1143. The FDA deems the following products to be components or parts of ENDS (sometimes referred to as "component parts"), and therefore will regulate them under the new rule: e-liquids and their containers, cartridges, atomizers, certain batteries, cartomizers and clearomizers, digital displays, programmable software, tank systems, drip tips, and flavorings for ENDS.

WHAT MUST MANUFACTURERS DO?

Notably, because they will now be regulated as tobacco products, ENDS and component parts cannot be sold or marketed to individuals under the age of 18. They also may not be sold in vending machines, unless the vending machine is in an adult-only facility.

The new regulations also require that manufacturers of ENDS or component parts obtain FDA approval to sell their products, subject to certain exceptions such as a "grandfather" provision that may be applicable to products sold on or before February 15, 2007. Manufacturers must submit a list of ingredients for their products, information on harmful and potentially harmful constituents (HPHCs) and tobacco health documents to the FDA. Furthermore, manufacturers of modified risk tobacco products, such as products advertised as less harmful than other tobacco products, must obtain an FDA order before selling such products.

WHAT WARNINGS ARE REQUIRED?

The new rule also requires warnings to be printed on all ENDS and component parts. 21 CFR 1143.3. If the product contains nicotine, the following warning must be placed on all packaging and advertisements:

> **WARNING: This product contains nicotine. Nicotine is an addictive chemical.**
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> On packaging, the warning area must be a least 30 percent of each of the two principal display panels. The exact language above must be printed directly on the packaging, clearly visible on the two principal display panels of the package, centered in the warning area, and printed in at least 12-point Helvetica bold or Arial bold font. If the packaging is black, the warning must be printed in white. If the packaging is white, the warning must be printed in black. If the packaging is too small to comply with this rule, the warning must appear on the carton or other outer container of the product, or on a tag affixed to the product.
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> The same warning language must be displayed on all advertisements for the product, including signs, shelf-talkers, Internet Web pages, and electronic mail correspondence. The warning area must occupy at least 20 percent of the area of the advertisement, with the warning text centered in the warning area in at least 12-point Helvetica bold or Arial bold font and surrounded by a rectangular border (between 3 mm and 4 mm) that is in the same color as the warning statement.
>
> A manufacturer may submit a statement to the FDA certifying that the product does not contain nicotine, if the manufacturer has data to support such a statement. If such a certification can be submitted for a product, then the packaging and advertisements for the product must include the following language instead of the language cited above:
>
> **This product is made from tobacco.**
>
> If the packaging or advertisement is printed in a language other than English, the warning must appear in that same language.

When Do the New Regulations Take Effect?

The new regulations will take effect on August 8, 2016. This means that the age restrictions and vending machine restrictions will apply on that date. By December 31, 2016, domestic manufacturers of ENDS must register establishments and submit product listings to the FDA. Most manufacturers will have two years, until August 8, 2018, to submit their applications to the FDA for approval to sell their products. In the meantime, manufacturers and sellers may continue selling their products in the usual course of their business, as long as they comply with existing federal and state regulations. Once applications are submitted to the FDA, a manufacturer may have an additional year to sell its products while the FDA considers its application.

The warning requirements discussed above will apply to all ENDS and component parts manufactured on or after May 10, 2018 and on all such products, regardless of manufacture date, beginning June 9, 2018.

The new FDA regulations will impose additional requirements on retail sellers, vape shops and importers of ENDS and component parts.

For additional information about the new FDA regulations governing e-cigarettes and related products in general, please contact Joy Syrcle, Michelle Corrigan Erikson, or the Stinson Leonard Street attorney with whom you regularly work.

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