

FDA Claims Jurisdiction Over All Tobacco Products

Law360, New York (August 5, 2016, 12:48 PM ET) --

On May 10, 2016, the U.S. Food and Drug Administration published its final rule extending the agency's regulatory jurisdiction over tobacco products to regulate e-cigarettes and certain other non-cigarette tobacco products, such as vape pens, *all* cigars, pipe tobacco and hookah products. In adopting the rule, the FDA is extending its "tobacco product" authority to cover *all* categories of products that meet the statutory definition of "tobacco product" and will enforce new regulations covering the advertising of tobacco products that have historically not been covered by the existing prohibition on advertising cigarettes and smokeless tobacco on television and radio stations. While the rule will become effective on Aug. 8, 2016, tobacco product retailers, manufacturers, importers and distributors will generally have until May 10, 2018 to come into full compliance with the new advertising health warnings and packaging requirements for newly-covered tobacco products.



Paul Cicelski

The new FDA rule regulates how tobacco products can be advertised and promoted. The FDA has repeatedly stated that the health warning requirements apply to all forms of advertising, regardless of the "medium in which it appears." The rule generally applies to retailers, manufacturers, importers and distributors of newly covered "tobacco products," which includes the specific regulation of e-cigarettes, and what the FDA calls all other electronic nicotine delivery systems (ENDS) (such as vaping devices). The FDA has indicated that, among other things, the final rule will subject all manufacturers, importers and/or retailers and distributors of newly-regulated tobacco products to the new FDA regulations, which will require parties to:

- Register manufacturing establishments and provide product listings to the FDA;
- Report ingredients, and harmful and potentially harmful constituents;
- Submit to a premarket review and authorization of new tobacco products by the FDA;
- Place health warnings on product packages and advertisements; and
- Not sell modified risk tobacco products (including those described as "light," "low" or "mild") unless authorized by the FDA.

In addition, there are new requirements targeted towards restricting access to tobacco products by minors, including:

- Prohibiting the sale of products to persons under the age of 18 years (both in-person and online);
- Requiring age verification by photo ID;

- Prohibiting the sale of tobacco products in vending machines (unless in an adult-only facility); and
- Prohibiting the distribution of free samples.

The rule has significant repercussions for the relatively new e-cigarette industry, which some have estimated to be a *\$3 to \$5 billion industry*. Prior to the FDA's action, there was no federal law specifically prohibiting retailers from advertising e-cigarettes. The FDA's decision to regulate the manufacture, labeling and sale of all covered "tobacco products," is a result of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009, which provide the FDA with the authority to regulate the tobacco industry.

In addition to e-cigarettes, the new regulations also apply to cigars (including so-called premium cigars), hookah (waterpipe) tobacco, pipe tobacco and nicotine gels. To be clear, although the new rule imposes direct obligations on the companies that advertise these products and not on the media running the advertisements, broadcasters should nonetheless be aware that any advertisements they receive from clients who manufacturer and sell covered "tobacco products" will eventually be required to include health warnings.

With respect to the broad health warning requirements of the new rule, product health disclosures will be necessary in *all means of packaging and advertising of tobacco products*. Included among the extensive FDA-provided list of advertising medium covered by the new rule include advertisements on *television, smartphones, internet websites and all "video and audio promotions."* The FDA has indicated that it intends to issue further guidance explaining how parties are to comply with the various individual rules applicable to different forms of advertising media, presumably including how the new regulations specifically impact broadcast television and radio advertising.

The parties subject to these new regulations should be sure to familiarize themselves with the rule's requirements, particularly because there are a number of different and staggered "effective" and "compliance" deadlines. These regulatory deadlines differ depending on whether the regulations pertain to the sale of tobacco products to minors, the required health warnings and packaging requirements, the new premarket review and other provisions that are part of the new rule. The specific content of the FDA-required warnings for the sale of the covered product varies depending on the product being advertised.

For example, unless otherwise noted, after Aug. 8, 2016, when the rule takes effect, ENDS retailers, manufacturers importers and distributors, will be required to take the following FDA-mandated steps:

1. Check photo ID of everyone under age 27 who attempts to purchase e-cigarettes or other ENDS.
2. Only sell e-cigarettes and other ENDS to customers age 18 and older.
3. NOT give away free samples of e-cigarettes or other ENDS, including any of their components or parts.
4. NOT sell e-cigarettes or other ENDS in a vending machine unless in an adult-only facility.

Further, as noted, beginning in May 10, 2018, parties will not be permitted to sell or distribute e-cigarettes or other ENDS without a health warning statement on the package and will not be permitted to display advertisements for e-cigarettes or other ENDS without a health warning statement.

The new FDA-required health warning disclosure for advertising e-cigarettes and other ENDS is the following:

“WARNING: This product contains nicotine. Nicotine is an addictive chemical.”

Similarly, all cigar product packaging and advertisements will be required to include warnings that follow specific size, format, rotational and distribution requirements. The full list of FDA-required health warnings for cigar advertisements, which must be rotated quarterly, is as follows:

1. **WARNING: This product contains nicotine. Nicotine is an addictive chemical.**
2. **WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.**
3. **WARNING: Cigar smoking can cause lung cancer and heart disease.**
4. **WARNING: Cigars are not a safe alternative to cigarettes.**
5. **WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.**
6. **WARNING: Cigar use while pregnant can harm you and your baby. (Or, as an optional alternative statement: SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.)**

As a result of the new rule, ads which promote the sale and use of e-cigarettes, other ENDS, or covered tobacco products, including cigars, could potentially be deemed to violate the rule. This determination depends on, among other things, the contents of the advertisement and how e-cigarettes or tobacco products are portrayed in the ad, and whether the ad meets the regulatory requirements of the rule going forward.

The FDA’s decision to adopt the new rule creates yet another layer of federal regulatory oversight over e-cigarette and tobacco product advertising. Existing advertising regulations enforced by the U.S. Department of Justice, Federal Trade Commission and the Federal Communications Commission, could also impact a determination of whether specific marketing practices and advertisements for e-cigarettes and other “tobacco products” are legally broadcast and otherwise distributed under federal law.

Additionally, it’s important to be cognizant that state and local governments also have their own authority to regulate e-cigarettes, as long as the regulations are not preempted by federal law. Indeed, state and local governments have, among other things, enacted smoke-free laws, taxed products and adopted certain retail and advertising restrictions regarding the sale of tobacco products (e.g., age requirements).

Given the broad scope of the FDA's new rule, it should come as no surprise that the FDA action adopting the rule has already been challenged by a number of e-cigarette manufacturers and trade associations in various federal courts. The lawsuits all generally claim that the FDA's regulatory scheme is too onerous and will be exorbitantly costly — particularly with respect to the FDA's premarket review and approval process for all products that were on the market after February 2007 — and will all but guarantee that the vast majority of e-cigarette and vaping products will be forced to leave the market due to the significant new regulatory burdens imposed by the FDA. These court proceedings remain pending and until a court or the FDA says differently, the new rule will take effect, as scheduled, on Aug. 8, 2016.

Despite the legal and regulatory minefield now applicable to the advertising and sale of e-cigarettes and other covered tobacco products, many advertisers, including radio and TV stations, are likely to continue to accept e-cigarette and other tobacco product advertisements in light of the millions of advertising dollars potentially at stake. By all accounts, the e-cigarette business is booming, so TV and radio stations, among others, can expect to continue to receive requests to air e-cigarette and other tobacco product advertisements. Only time will tell how the new regulations will impact the tobacco and e-cigarette industries, and whether the rule will survive the court challenges. That said, broadcast stations and other media outlets should now become even more vigilant in vetting such advertisements prior to their release.

—By Paul Cicelski, Lerman Senter PLLC

Paul Cicelski is an attorney at Lerman Senter in Washington, D.C.

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