

HEALTH ADVERTISEMENTS AND SMOKING PRODUCTS

Health Claims and Warnings

In recent months, the MPA Hotline Team has seen a significant uptick in advertising of products that have health claims or should be accompanied by health warnings. These ads are of special concern as the FTC has enhanced its guidance and enforcement in this growing area of ad revenue.

The challenges faced by health related claims in advertising can be found in the federal law. It is unlawful under the FTC Act to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made (15 U.S.C. § 41 *et seq*). Additionally, some products must have special disclaimers or warnings, including those products containing nicotine under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 387c).

E-Liquids and “Vape Juices”

E-liquids, e-juices or vape juices are the mixture of food grade flavoring, water, other chemicals and sometimes nicotine that are used in vaporizers and electronic cigarettes. On June 7, 2019, the FTC issued warning letters to manufacturers of flavored e-liquids who use influencers that did not disclose material health or safety risks in their content. The FTC reminded advertisers and companies that “ads must disclose ... the fact that nicotine is highly addictive” and other disclaimers that would be found on traditional cigarettes. The letter urged companies to conduct a review of all marketing strategies and especially demanded that influencers include the required disclosures.

Be advised that JUUL devices were banned by the FDA, but the ban is currently stayed pending a court case to address whether the ban was arbitrary.

Dietary Supplements

Other recent actions and comments from the FTC include dietary supplements, another area of high scrutiny. The guidance on these products detail the type of evidence required to make claims about the effectiveness of supplements and the inferences that an advertiser can draw. But supplements aren’t the only space the FTC is concerned about health claims.

CBD Oil

On March 29, 2019, the FTC issued letters to three cannabidoil (CBD) manufacturers based on advertisements of their products. The claims made, which are mostly unsupported by peer-reviewed scientific evidence, include the treatment of cancer, Alzheimer’s disease, fibromyalgia and other “neuropsychiatric” disorders. In the letters, the FTC noted that CBD oil has not been found to be a supplement and such claims place it squarely in the realm of a drug. When CBD oil is advertised as a drug, it would require FDA approval and additional advertising considerations, none of which were present in the manufacturers’ initial advertising.

Smokeless Tobacco - Required Warning Statements

Since July 22, 2010, smokeless tobacco product packaging and advertising must bear one of the following required warning label statements, per section 3 of the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), as amended by section 204 of the Tobacco Control Act, in accordance with an FDA approved warning plan:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

Cigars - Required Warning Statements

As of August 10, 2018, all cigar packages that are manufactured, packaged, sold, offered for sale, distributed, or imported for sale or distribution within the United States must bear one of the following required warning statements, per 21 CFR § 1143.5(a)(1), on the package label:

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby.

-OR-

SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.*

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

*You may choose to display either one of the warning statements regarding reproductive health. FDA expects that providing this optional alternative will benefit entities bound by the Federal Trade Commission (FTC) consent decrees, and the statement is appropriate for the protection of public health.

Cigarettes - Required Warning Statements

Any person who manufactures, packages, or imports for sale or distribution cigarettes within the United States must continue to comply with the requirements for cigarette health warnings under the Federal Cigarette Labeling and Advertising Act (FCLAA), as in effect before amendment by the Family Smoking Prevention and Tobacco Control Act.

15 U.S.C. §§ 1331-1340; 21 U.S.C. § 387c

§ 1333. Labeling; requirements; conspicuous statement

(a) Required warnings; packages; advertisements; billboards

(1) It shall be unlawful for any person to manufacture, package, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.

"Covered" Tobacco Products and Roll-Your-Own/ Cigarette Tobacco Labeling and Warning Statement Requirements

Beginning August 10, 2018, you cannot manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States roll-your-own, cigarette tobacco, or "covered tobacco products" without the required warning label statement on the tobacco product package, per 21 CFR § 1143.3(a)(1). (Cigar required warnings are described under 21 CFR § 1143.5.)

For the following products, including components and parts, that are sealed in final packaging intended for consumer use and are made or derived from tobacco, package labels and advertisements must bear the nicotine addictiveness warning statement:

- hookah
- pipe tobacco
- vaporizers, e-cigarettes, and other electronic nicotine delivery systems (ENDS)
- dissolvables
- gels
- roll-your-own and cigarette tobacco

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

Zero-Nicotine: Self-certification and Alternative Required Warning Statement

If the product does not contain nicotine and is made or derived from tobacco, the tobacco product manufacturer may display the alternative warning statement, instead of the nicotine addictiveness warning statement.

The alternative warning statement, under 21 CFR § 1143.3(c), for applicable package labels and advertisements reads:

"This product is made from tobacco."

Products that are not made or derived from tobacco do not meet the definition of "covered tobacco product" and are not required to carry any of the required warnings or to submit a self-certification.

What does this mean for me?

1. Monitor your ads for health claims!

With the uptick in supplement sales, changes in marijuana law and the introduction of CBD oils, many companies are excited to tout the restorative and therapeutic value of these types of products. Even if you're not using sponsored content or influencers in this area, the content of these ads must still be monitored to assure that an advertiser isn't extending claims that cannot be verified.

- Look at the claims the ad is making and beware if the data cited in the ad doesn't support the claim
- Think about whether the product may require "qualifying" information including product safety risks
- Make sure these risks are clear and prominent in any submitted ad
- Call the MPA Hotline if you are concerned about these ads, especially if you find yourself worrying about the amount and type of evidence used or the type of product (especially CBD or marijuana)

2. Watch out for ads requiring health disclaimers!

Just like making sure a cigarette ad contains the appropriate disclaimers, e-cigarette related products like e-liquids have additional requirements.

- Watch for advertisements that sell e-liquids and determine whether they contain nicotine
- Verify that the appropriate nicotine disclaimers are present in the ad