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Practical guidance for an ever-changing world

The FDA Sends Over 60 Warning Letters to Companies for Falsely Marketing "COVID-19 Products"

In the wake of the global pandemic caused by the novel coronavirus, the U.S. Food and Drug Administration (FDA) has issued dozens of warning letters to various companies — including so-called 'affiliate marketers' — asserting that they have fraudulently marketed products that claim to prevent, treat, mitigate, diagnosis or cure COVID-19. These products include vitamin and mineral products, essential oils, colloidal silver, CBD oils and many others.

FDA Guidance

The FDA has stated that it has taken a number of steps to police fraudulent products in order to protect consumers against scams and the potential harm in utilizing ineffective products in lieu of other preventative measures and treatments. Any product coming to the FDA's attention is likely to result in the FDA publicly ordering the company and/or its affiliate marketing partners to correct the violations, including by ceasing the use of such claims.

Background

If a product is intended to diagnose, prevent, treat, mitigate, or cure a disease, the product is considered a drug by the FDA. Any drugs considered to be new drugs, marketed or offered for sale in the United States require prior approval from the FDA before being sold to consumers. In contrast, nutritional or dietary supplements do not require prior approval from the FDA, provided that the marketing, packaging and sale of such products is compliant with all applicable regulations.

The Bottom Line

Marketers and affiliate marketers of supplements, oils and similar products regulated by the FDA must be extremely cautious about referring to COVID-19 or its symptoms in marketing communications about such products.

Statements that might otherwise be acceptable will likely be considered impermissible when used in conjunction with references to COVID-19, its symptoms or any other disease or disease category.

Marketers can expect the FDA to take action against products making claims about the ability of the product to diagnose, prevent, treat, mitigate or cure COVID-19.

ADVERTISING, MARKETING & PROMOTIONS

Marketing Claims About Supplement Products in Relation to COVID-19

Companies are not allowed to make marketing claims about their supplement products in relation to COVID-19. Almost any supplement product statement that explicitly refers to COVID-19 by name is likely to result in the FDA categorizing the product as an unapproved drug. Any such product would require specific approval from the FDA before being marketed or made available for sale in the United States.

For example, certain dietary supplements are able to be marketed with the claim that such products 'help support the immune system,' provided there is adequate scientific support that the product does, in fact, help support the immune system, and provided the product is in compliance with all other regulations (*e.g.*, among other things, the product packaging must include the disclaimer: *"This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."*). When such circumstances are met, FDA pre-approval is not required.

However, where a supplement product's marketing specifically refers to COVID-19, the otherwise permissible statement will now likely be considered to constitute an impermissible claim that the product can prevent, treat, cure or mitigate COVID-19.

Even if the supplement product does not specifically refer to COVID-19, and instead refers to the product's ability to treat the *symptoms* of COVID-19, such as shortness of breath, fever, or flu-like symptoms, the FDA will likely determine the product is a drug requiring approval from the FDA.

In the absence of FDA approval for a product to be used as a drug, a product making a claim that it can diagnose, prevent, treat, mitigate or cure COVID-19 (or any other disease) will, if scrutinized by the FDA, be deemed unapproved and/or misbranded.

For More Information

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