Health Industry Alert

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FDA Explains Current Thinking on CBD and Issues Targeted Warning Letters

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On November 25, the Food and Drug Administration (FDA) issued 15 warning letters to companies selling products containing hemp-derived cannabidiol (CBD) and released a summary of its approach to the regulation of CBD products.

FDA issued these recent warning letters to companies marketing CBD products with health benefit claims, including claims that the product will treat conditions such as cancer, anxiety, pain and inflammation. Keeping in line with prior warning letters FDA has issued regarding CBD, FDA asserts that these claims render the products unapproved new drugs in violation of the Federal Food, Drug and Cosmetic Act (FDCA).

Further, the warning letters discuss FDA's view that the FDCA prohibits the sale of food or dietary supplements containing CBD. In announcing the warning letters, FDA stated that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for use in human or animal food. The warning letters also focus on CBD products that are being marketed to children.

Thus far, FDA enforcement action within the CBD space has been limited to warning letters. The agency has not taken additional action, such as seeking an injunction or seizing CBD products. FDA has also limited its warning letters to products that make health benefit claims.

In addition to the warning letters, FDA posted a revised consumer update regarding CBD. In the consumer update, FDA expresses concern regarding the potential risks associated with using CBD, such as liver injury, drug interactions and male reproductive toxicity. However, the consumer update does not detail at what dosage levels these risks arise.

Notably, FDA's actions do not preclude it from adopting a more formal enforcement discretion policy in the future. Indeed, Senate Majority Leader Mitch McConnell (R-KY) has introduced appropriations committee report language that calls for FDA to issue an enforcement discretion policy regarding CBD products within 120 days of the enactment of FDA's appropriations. Congress is currently working to pass the bill prior to December 20.

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The legal and policy status of CBD has been changing significantly since the 2018 Farm Bill removed some CBD products from the list of controlled substances. Congress and FDA are considering further changes. Regulated industry, investors and other stakeholders should continue to monitor this area and provide input to policymakers as appropriate.

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