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New Day, Same Story: FDA Issues Additional Warning Letters for Sale and Marketing of Hemp-Infused Human and Animal Products

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This week, the U.S. Food & Drug Administration (FDA) posted warning letters to five hemp companies for, in the words of the FDA, 'illegally selling products containing cannabidiol (CBD).'

The warning letters and additional commentary from the FDA can be accessed for a full review here. Since the passage and enactment of the 2018 Farm Bill, which removed hemp and tetrahydrocannabinol (THC) found in hemp from the Federal Controlled Substances Act, the FDA has consistently asserted regulatory control over certain aspects of the hemp industry pursuant to the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations. Chief among those regulatory concerns has been the FDA's position that it is unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements regardless of whether the substances are hemp-derived. You can read more about the background and history of this and the FDA's prior warning letters here, here, or on a number of other news, regulatory, and legal sites across the internet.

The batch of letters posted to the FDA's website this week continues the long line of warnings sent to companies operating in the hemp-derived cannabinoid space. It is not readily apparent why the FDA chose to single out these companies, in particular, for enforcement. But the letters released this week, as a group, seem to intentionally target and address the following common activities:

- Sale and marketing of products intended for ***human*** consumption that contain added CBD or THC in a form that consumers may confuse with foods.
- Sale and marketing of products that pose a risk of unintended consumption of CBD or THC by consumers, including failure to label CBD as an ingredient on product labels (for example, simply listing "full spectrum hemp extract" on the product label).
- Sale and marketing of products in forms that are appealing to children, like lollipops, gum, and candies.
- Combination of CBD with caffeine in products, because "CBD may affect caffeine metabolism and may increase and/or prolong caffeine's effects."
- Sale and marketing of ***animal products*** containing added CBD or THC for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals. And,

- The sale and marketing of ***animal foods and pet treats*** that are adulterated by adding CBD and other cannabinoids.

To date, the FDA's prior enforcement actions have largely centered on companies selling or marketing human- or animal-related hemp products in connection with unauthorized claims to cure, mitigate, treat, or prevent various diseases and health-related conditions. But in an important departure from the FDA's past practice, less than all of the warning letters released this week reference alleged FD&C Act health claim violations by the companies. So what does that mean? Are these letters a precursor to an onslaught of new industry warnings to come? Does this signal that the FDA is gearing up to devote more of its enforcement efforts and energies to regulate the use of CBD, THC, and other cannabinoids in situations where companies are intentional and careful **not** to make prohibited health-related claims about their hemp products?

While this group of warning letters may mark a shift in the FDA's ongoing regulatory enforcement focus, it does not appear to significantly change the industry's overall legal and regulatory risks in prior years. Much of what the FDA states in these letters has been incorporated into its prior warnings to the industry. But it remains important for hemp product manufacturers and sellers to carefully and continuously monitor and consider the FDA's position on CBD, THC, and other cannabinoids utilized in food and supplement products and to incorporate that position into their internal compliance practices as they develop, market, and sell hemp products in interstate commerce.

Ward and Smith's **Hemp + Cannabis Law** attorneys are actively helping individuals and businesses navigate the complex and rapidly changing state and federal laws and regulations governing these industries and their products.

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