Updates
October 25, 2019

FDA and FTC Take More Forceful Tone With CBD Manufacturer

The U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) sent a joint warning letter on Tuesday, October 22, 2019, to Rooted Apothecary, LLC, alleging that the Florida-based company has been making egregious advertising claims. As described in the FDA's enforcement update, Rooted Apothecary sold "products containing cannabidiol (CBD) online with unsubstantiated claims that the products treat teething pain and ear aches in infants, autism, attention-deficit/hyperactivity disorder (ADHD), as well as Parkinson's and Alzheimer's disease, among other conditions or diseases."

Previously, FDA and FTC enforcement activity has been limited to sending warning letters. However, this time, the agencies have gone a step further, **requesting that Rooted Apothecary provide responses within 15 business days explaining "how the company will correct the violations," and threatening that failure to do so promptly could result in legal repercussions, including product seizure and/or injunctions.** While more aggressive than past warning letters, the agencies' requests and threats are consistent with their expressed positions on CBD advertising claims, as well as with prior recommendations from Perkins Coie regarding how companies in the CBD industry can mitigate risks:

- Limit marketing to general terms such as "maintain," "support" and "promote" (i.e., "contains calcium to support strong bones") in CBD advertising.
- To the extent possible, describe the role of the nutrient or ingredient intended to affect the human body's normal structure or function.
- To the extent possible, substantiate claims, and avoid claims that are difficult or not possible to verify, such as "CBD gummies can help treat cancer."
- Ensure express and implied health claims are supported by competent and reliable scientific evidence.

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