FDA and FTC Issue Joint Warning Letters to Three Online CBD Marketers

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The FDA and FTC jointly issued warning letters to three companies selling CBD products online. The letters allege violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Federal Trade Commission Act ("FTCA"). Although this is the first time the FDA and FTC have issued joint warning letters relating to CBD, the FDA has been involved in CBD enforcement for the past few years.

Since the passing of the 2018 Farm Bill, which descheduled hemp and hemp derivatives under the federal Controlled Substances Act, the FDA has become the primary federal regulator relative to foods, drugs, cosmetics, and dietary supplements that contain CBD from hemp. The FDA's most visible enforcement on CBD products to date has been in the form of warning letters issued to online retailers of products labeled as dietary supplements that feature aggressive disease treatment claims. The FDA also tested CBD products in conjunction with warning letters issued in 2015 and 2016 to determine whether they contained the CBD levels listed on the labels.

In the letters from last week, the FDA turned its focus onto various CBD products marketed online as "drugs," including "CBD Salve," "CBD Oil," "CBD for Dogs," "Hemp Oil," "CBD Softgels," "Liquid Gold Gummies (Sweet Mix)," "Liquid Gold Gummies (Sour Mix)," and "blue CBD Crystals Isolate 1500mg." The FDA determined that the companies' websites contained claims about their CBD products that established them as unapproved "drugs" under section 201(g)(1) of the FDCA. The letters also referenced the FTC's substantiation standard, stating the FTC had concerns that certain efficacy claims that were made may not be substantiated by competent and reliable scientific evidence. They also warned that violations of the FTCA may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order, possibly including a requirement to pay back money to consumers.

As noted above, these letters are unique, as it is the first time the FDA has issued a joint FDA/FTC warning letter relating to CBD. This is also the first time the FDA has referenced the FTC's substantiation standard or threaten any specific penalty for violations of the FTCA. For companies marketing CBD, it is important to keep in mind that although the market has flourished despite a host of regulatory uncertainties, it is the regulators' opinion that the rules regarding advertising and health claims are clear. Competent and reliable scientific evidence remains the standard.

Over the last few years, however, the FTC's health claim enforcement has featured several false cure-type products. Cases against Regenerative Medical Group, Cellmark, iV Bars, and Nobetes challenged unproven representations for products promising to treat Parkinson's disease, macular degeneration, cancer, multiple sclerosis, and diabetes. Although we have yet to see the FTC announce any settlements relating to CBD products, these letters signal that FDA is not alone in its

concern over aggressive CBD treatment claims.

The warning letters can be found here:

- Advanced Spine and Pain, LLC (d/b/a Relievus)
- Nutra Pure LLC
- PotNetwork Holdings, Inc.