

March 18, 2019

CHPA supports efforts to encourage FDA to develop a legal path for CBD as a new dietary ingredient. Hemp oil is already an appropriate dietary ingredient.

The 2018 farm bill makes hemp production more practical by excluding hemp that contains less than 0.3% tetrahydrocannabinol (THC) from the definition of marijuana and removing it from the Controlled Substances Act. Meanwhile, state law varies considerably concerning cannabidiol (CBD) specifically and cannabinoids in general, and the field has a number of uncertainties. In light of this, CHPA's position follows.

1. A path for drugs already exists. The existing drug approval process provides a pathway for sponsors to develop data to bring cannabis-derived products to market once shown safe and effective. Indeed, FDA has already approved the prescription drug Epidiolex (highly-purified CBD). CHPA supports the new drug path for cannabis-derived products that make disease-related claims, either prescription or OTC, that are supported by appropriate evidence with FDA-approved labeling.

2. A legal new dietary ingredient path for CBD is needed. Notwithstanding the presence of numerous products on the market claiming CBD in dietary supplements, FDA has taken the position that CBD cannot be lawfully included as an ingredient in a dietary supplement as it has been authorized for investigation as a new drug and FDA is not aware of prior marketing as a food or dietary supplement. CHPA supports FDA's position.

However, FDA has authority to develop a regulation to allow CBD to be a lawful dietary supplement ingredient through the new dietary ingredient (NDI) path. The new dietary ingredient path requires sufficient information to provide reasonable assurance the ingredient does not present a significant or unreasonable risk of illness or injury. CHPA supports FDA moving forward with such a regulation.

3. Enforcement should increase. With or without a legal NDI path, marketers of CBD-containing drugs masquerading as supplements threaten to undermine consumer confidence and may pose risk. FDA should increase enforcement actions against dietary supplements claiming to contain CBD, particularly those that make unlawful, outlandish, and unsubstantiated drug claims. Supplements, with or without CBD, may not be intended to treat, cure, or mitigate a disease. A manufacturer is ultimately responsible for generating appropriate scientific support to make truthful, not misleading claims.

4. Hemp oil is already an appropriate dietary ingredient. An exception in the law allows a substance to be marketed as a dietary supplement or conventional food if the substance was marketed as a dietary supplement or conventional food before a new drug investigation was authorized. Hemp or hemp oil has been used in food and supplements since at least the early 2000s.¹ Therefore, CHPA supports the view that hemp oil, including hemp oil with naturally occurring CBD, is an appropriate dietary supplement ingredient.²

FDA and stakeholders should work together to further develop pathways for hemp and CBD-containing products, both medicines and dietary supplements, to safely reach consumers.

CBD_hemp_oil_position-18March2019

¹ Hemp Industries Assoc. et. al. v. DEA (Case No. 03-71366). See 1791, FN 2 ("Appellants list a wide range of current and planned commercial products that use hemp oil or seed, including roasted hulled seed, nutrition bars, tortilla chips . . .").

² FDA recently declared three hemp-seed derived food ingredients as generally recognized as safe (GRAS): hulled hemp seed, hemp seed protein powder, and hemp seed oil. See <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm628910.htm>