Language Permitting CBD to be Used in Dietary Supplements

Ag Approps Bill Language:

Notwithstanding 21 U.S.C. § 321(ff)(3)(B), cannabidiol derived from hemp (as defined in 7 U.S.C. § 1639o(1)) shall be considered a lawful dietary ingredient for use in a dietary supplement for purposes of the Food, Drug and Cosmetic Act (FDCA) provided that: (a) any such dietary supplement offered for sale in interstate commerce complies with the applicable requirements for a new dietary ingredient in 21 U.S.C. § 350b; and (b) a dietary supplement that contains the ingredient complies with all other requirements for a dietary supplement in the FDCA, including that the product does not bear any claims on its label or in its labelling that are for indications that are the subject of any approved new drug under 21 U.S.C. § 355, certified as an antibiotic under 21 U.S.C. § 357, or licensed as a biologic under 42 U.S.C. § 262.

Accompanying Report Language:

Authorizing language has been included in the bill following enactment of the 2018 Farm Bill to clarify that there is a legal pathway for cannabidiol (CBD) derived from hemp to be sold as dietary supplements. Given the prevalence of CBD products in the marketplace, the Committee believes it would be reasonable to provide companies selling these products 180 days from the date of enactment of this Act to comply with the applicable requirements for a new dietary ingredient in 21 U.S.C. § 350b. An additional **$xx** million has been included in the bill for FDA to effectively oversee this fast-growing category, including for efficient and timely review of new dietary ingredient notifications and enforcement of consumer protection laws governing the safety, manufacturing and labeling of dietary supplements among currently marketed CBD products.