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FDA identifies pathways for hemp ingredients in food & supplements

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Commissioner Gottlieb issues statement on 2018 Farm Bill and “cannabis-derived compounds”

Within an hour of the signing ceremony for the historic 2018 Farm Bill, the Food and Drug Administration (FDA) issued a statement by Commissioner Dr. Scott Gottlieb on the agency’s regulation of products containing “cannabis and cannabis-derived compounds,” in which the Commissioner acknowledged there are “pathways” for FDA to consider “circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement.”

As AHPA reported yesterday, President Trump has now signed the 2018 Farm Bill (formally the Agriculture Improvement Act of 2018), which includes provisions that eliminate several federal barriers to the cultivation, production, and commercial development of hemp and hemp products, and that remove hemp from Schedule I of the Controlled Substances Act. “Hemp” is now defined as “the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol [THC] concentration of not more than 0.3 percent on a dry weight basis.”
Dr. Gottlieb’s statement noted that the Farm Bill preserves FDA’s current authority to regulate products containing cannabis or cannabis-derived compounds, and declared that such ingredients – clearly including hemp and hemp derivatives, such as cannabidiol (CBD) – are treated “as we do any other FDA-regulated products.”

The Commissioner also restated FDA’s concerns over “drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds,” as well as the agency’s position that under the Food, Drug and Cosmetic Act (FD&C Act) it is “unlawful … 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.”

Importantly, Dr. Gottlieb also emphasized that FDA "has authority to issue a regulation" that would allow these naturally-occurring hemp compounds in a food or dietary supplement. He also stated that FDA is now evaluating whether to pursue such a process, and clarified that the agency "would only consider doing so" if it determines "that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients."

"The food and supplement industry should read Dr. Gottlieb's statement first and foremost as an indication that FDA shares our desire for hemp and CBD products to be properly regulated under federal law, and now recognizes its statutory authority to address the agency's view of the prior-drug status of some Cannabis compounds through rulemaking," noted AHPA President Michael McGuffin. "The relevance of this authority was first seen by AHPA's Cannabis Committee over two years ago, and AHPA identified this publicly in May of this year as an approach that FDA should be encouraged to consider."

"At the same time, the Commissioner's emphasis on the legal requirements that must be met for food additives or new dietary ingredients (NDIs) is a clear signal of FDA's thinking, and we should not be surprised if any forthcoming FDA action focuses on compliance with the law's provisions for NDI notifications for supplement ingredients, and for hemp ingredients used in foods to meet the provisions to establish these as generally recognized as safe (GRAS) under the law," added McGuffin.

Commissioner Gottlieb's statement also announced that FDA intends to convene a public meeting in the near future to discuss products that contain hemp-derived ingredients, including food and supplement products.

"AHPA has been engaged in issues related to the safe use and responsible commerce of lawfully marketed products derived from Cannabis since 2010 and we will continue to actively participate in any and all relevant FDA meetings and rulemaking activities," noted Jane Wilson, AHPA's Director of Program Development and liaison to the AHPA Cannabis Committee.