

May 31, 2019

FDA Public Meeting: Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

Statement of Michael McGuffin President, American Herbal Products Association

Good morning. My name is Michael McGuffin and I am the president of the American Herbal Products Association, or AHPA. Aside from my statement here, AHPA will submit detailed written comments to the docket.

AHPA understands that the 2018 Farm Bill reflected the intent of Congress to allow broad access to hemp and products derived from hemp, including those containing cannabidiol, or CBD.

Even prior to the Farm Bill's enactment, FDA stated its position, with which AHPA has neither agreed nor disagreed, that provisions of the FD&C Act prohibit marketing CBD dietary supplements and adding CBD to conventional foods. AHPA notes that these provisions should not preclude use of hemp-derived ingredients containing naturally occurring quantities of CBD, and urges FDA to publicly acknowledge this important distinction.

FDA's position on CBD has resulted in significant marketplace confusion. Many companies now selling foods and supplements containing CBD have the mistaken impression that FDA does not currently regulate them; others have chosen to stay out of the market based on FDA's position.

To fully implement Congress's intent to allow access to products that contain hempderived CBD, and to further AHPA's and FDA's shared goal of ensuring safe and wellmanufactured supplements and foods, AHPA requests that FDA promptly take one of the two following actions:

- FDA should use its authority under the FD&C Act to issue a regulation possibly as an interim final rule with an accelerated effective date permitting CBD as a lawful ingredient in supplements and foods. Of course, this regulation would still require compliance with all other applicable federal regulations.
- Alternately, and especially if FDA cannot issue this requested regulation promptly, FDA should issue guidance to state the Agency's intent to exercise formal enforcement discretion with respect to the provisions of the FD&C Act on which FDA bases its position that CBD-containing supplements and foods are unlawful. AHPA would support conditioning this exercise of enforcement discretion on full compliance with all other regulations applicable to these categories.

FDA has previously acknowledged its authority to create a lawful pathway for marketing CBD-containing supplements and foods, and the Agency should act promptly to use this authority.

Thank you.