



THE VOICE OF FOOD RETAIL

Feeding Families  Enriching Lives

July 16, 2019

Dockets Management Staff (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments; Docket No. FDA-2019-N-1482**

To Whom It May Concern:

On April 3, 2019, the Food and Drug Administration (FDA or the Agency) published in the *Federal Register* a notice announcing a public hearing and the establishment of a docket to receive information regarding products containing cannabis or cannabis-derived compounds. The Food Marketing Institute (FMI) thanks the FDA for the opportunity to submit comments, and appreciated the Agency convening stakeholders to further the discussion around this important topic.

FMI proudly represents the food retail industry, including the entire spectrum of food retail venues – from single owner grocery stores and large multi-store supermarket chains, as well as their pharmacies, to online and mixed retail stores. In total, FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. Through programs in food safety, health and well-being, public affairs, research, education and industry relations, FMI offers resources and provides valuable benefits to almost 1,000 food retail and wholesale member companies, while serving 85 international retail member companies. In addition, FMI has almost 500 supplier member companies that provide products and services to the food retail industry. For more information about FMI, please visit [www.fmi.org](http://www.fmi.org).

### **Introduction**

Health and well-being is of the utmost importance to food retailers, and for years, FMI and its member companies have recognized the value of listening to our customers' needs and helping them navigate the abundance of products on the market, as well as their health-related claims. At the same time, FDA plays a critical role in promoting public health, including among other priorities, helping to ensure that consumers can make informed choices about the products they purchase. Moreover, public health and safety should always be the top priority when introducing new consumer products into the market.

**With that in mind and given the burgeoning market for hemp and hemp-derived products, especially those containing cannabidiol (CBD), we were encouraged by FDA Principal Deputy Commissioner Amy Abernethy's recent announcement that "FDA is expediting its work to address the many questions**

**about [CBD].”<sup>1</sup> FMI respectfully urges FDA to move swiftly to provide guidance on a lawful pathway to market for hemp-derived CBD products in order to ensure such products meet applicable quality and labeling standards, as deemed appropriate by FDA. Furthermore, in addition to uniform quality and labeling standards, we also request consistency in enforcement across distribution channels.**

### **Background**

On December 20, 2018, President Trump signed the Agricultural Improvement Act of 2018 ([the Farm Bill](#)) into law with several provisions that changed the regulatory framework regarding the production of hemp in the U.S., in addition to the commercialization of hemp-derived ingredients and products. Importantly, these provisions redefined “hemp” and amended the Controlled Substances Act to make clear that hemp, under this revised definition, is no longer a controlled substance. As a result, it has been widely reported that the Farm Bill “legalized” hemp and hemp derivatives, such as CBD, which has generated significant attention in recent months.

Importantly, however, FMI understands that passage of the Farm Bill did not preempt state law regarding the manufacturing and/or sale of products containing hemp or hemp-derivatives, nor did it alter the FDA’s authority over the use of hemp or hemp-derivatives in FDA-regulated products. We also understand FDA’s current position is that hemp-derived CBD cannot be legally marketed as an ingredient in food, beverages or dietary supplements. Despite FDA’s position, the number of CBD-containing foods, beverages, and dietary supplements on the market continues to grow. The patchwork of state laws regulating cannabis and cannabis-derived products, coupled with the lack of federal standards for the use of hemp-derived CBD in manufactured products, has created mass confusion for the public, suppliers and retailers, and also state regulators.

### **The Need for Regulation**

Consumer interest in hemp and hemp-derived products, especially those containing CBD, is already significant and continues to grow rapidly; from ingestible products, including foods, beverages and dietary supplements, to topical products, such as creams and lotions – for both human and animal use. A recent [Consumer Reports survey](#)<sup>2</sup> found that more than a quarter of Americans say they’ve tried CBD, while one out of seven of those people said they use it every day. Given the significant consumer interest, more and more companies are taking steps towards entering this space. Sold in pill form, foods, oils, tinctures, topical lotions, and even in bottled water and cosmetics, CBD is already in countless products on the market.

That said, the absence of a clear pathway to market for CBD-containing foods, beverages, and dietary supplements to date means consumers currently face a variety of risks, from unsubstantiated health and

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<sup>1</sup> Dr. Amy Abernathy. (2019, July 12). FDA is expediting its work to address the many questions about cannabidiol (CBD). This is an important national issue with public health impact, & an important topic for American hemp farmers and many other stakeholders. <https://twitter.com/DrAbernathyFDA/status/1149766446106497025>

<sup>2</sup> Gill, L. (2019, April 11). *CBD Goes Mainstream*. Retrieved from Consumer Reports: <https://www.consumerreports.org/cbd/cbd-goes-mainstream/>

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benefit claims, to a lack of standardization in product labeling and packaging, to products that may not contain the ingredients it purports to contain. Furthermore, given the consumer demand and the desire of our members to provide products their customers are seeking, we are fielding more and more questions from companies that are understandably seeking clarity about the current regulatory framework for the sale and labeling of products containing CBD. And, while FMI members always want to be in full compliance with FDA regulations, we also want to ensure our members have appropriate assurances that the products they're merchandising are both safe and being sold appropriately. In short, the market is far too large to remain unregulated, and the current lack of FDA regulation is creating significant confusion in the marketplace.

FMI respectfully urges FDA to move expeditiously to provide additional clarity and establish a pathway forward for the use of hemp-derived ingredients, including CBD, in FDA-regulated products. The safety concerns and marketplace confusion surrounding hemp and hemp-derived products will continue until FDA provides guidance governing the production, sale, quality and marketing of these products. To that end, we urge FDA to develop thoughtful guidance around the sale of FDA-regulated products containing CBD and other hemp-derived ingredients that meet consumer expectations and demands, while also ensuring the safe marketing of these products for appropriate intended uses. This guidance would also be a tool to help facilitate consistent enforcement and oversight. More specifically, clarity regarding the saleability, labeling and quality standards for these products would promote consistency in enforcement regardless of the distribution channel through which these products are marketed.

In conclusion, FMI sees the regulatory challenges surrounding the legal and appropriate sale of hemp and hemp-derived products, especially those which count CBD as an ingredient, as a critically important policy issue, and we urge the Agency to consider our input as this process moves forward.

On behalf of the supermarket industry, FMI appreciates the opportunity to provide these comments.

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If you have questions about these comments or would like additional information, please feel free to contact me or Peter Matz ([pmatz@fmi.org](mailto:pmatz@fmi.org)) at (202) 452-8444.

Sincerely,



Leslie G. Sarasin  
President and  
Chief Executive Officer