



American Society for Nutrition
Excellence in Nutrition Research and Practice

July 9, 2019

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane; Room 1061
Rockville, MD 20852

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

Dear Sir or Madam:

The American Society for Nutrition (ASN) appreciates the opportunity to comment on “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds.” ASN brings together the world’s top researchers to advance the knowledge and application of nutrition. ASN has more than 6,500 members working in academia, public health, clinical practice, industry, and government who enhance scientific knowledge and quality of life through excellence in nutrition research and practice.

Given the current patchwork of state legislation related to cannabis and cannabis-derived compounds and passage of the Hemp Farm Act in the 2018 Farm Bill, it is important that the FDA clarify under which circumstances research is allowable for food products and dietary supplements that contain hemp, cannabis, and hemp- and cannabis-derived compounds such as tetrahydrocannabinol (THC) and cannabidiols (CBD). ASN requests that the FDA not be overly restrictive when determining the allowable circumstances for such research, as safety studies are urgently needed to help us better understand the health effects of cannabis and cannabis-derived compounds in food products and dietary supplements. It is also imperative that U.S. federal agencies including the FDA conduct and support research regarding the health and safety effects of products that contain cannabis and cannabis-derived compounds to help advance our understanding. Following the 2018 Farm Bill’s legalization and reclassification of hemp as an agricultural product, it is also important to support research to understand the nutritional value and health effects of food products that contain hemp and hemp-derived compounds such as hemp seeds, oils, protein powders, and more.

ASN urges FDA to provide uniform structure and safety to a food category that is rapidly growing, yet largely unregulated. According to Nutrition Business Journal, U.S. sales of CBD and hemp oil products containing CBD reached \$238 million in 2018, up 57 percent from 2017. According to the National Restaurant Association’s Culinary Forecast: Top Trends Chefs Identified for 2019, the number one and number two trends are cannabis/ CBD oil-infused drinks and cannabis/ CBD oil-infused food, respectively. However, studies have found that food products and dietary supplements currently available to consumers containing cannabis

and cannabis-derived compounds are often mislabeled and contain widely varying amounts of CBD and/or THC, often at levels other than what is indicated on the label. It would also be useful for the FDA to establish thresholds of safe and acceptable levels of cannabinoids, including CBD, in the non-drug products it regulates.

Additionally, with regards to product quality, safety, and labeling, it is necessary that FDA develop and enforce standardized definitions for products that contain hemp, cannabis, and hemp- and cannabis-derived compounds. Such definitions and labeling requirements should address safe and acceptable levels of cannabis-derived compounds including concentrate and isolate forms, as well as synthetic vs. plant-derived. ASN also has concerns with current labeling that inappropriately indicates food products and dietary supplements that contain cannabis and cannabis-derived compounds may be used to manage and/or treat a disease or health condition when research to validate such claims is not provided.

Since classification as a Schedule I substance in 1970, research regarding the health effects of cannabis and cannabis-derived compounds, including necessary research on safety such as proper dosing, ratios, efficacy, and potential drug and food ingredient interactions has been stalled. This has resulted in a considerable research gap concerning the future impact of a growing multimillion-dollar industry. Research indicates that the mode of delivery of cannabis and cannabis-derived compounds (ingestion vs. absorption, inhalation, etc.) has dramatically different health-related effects and more research is needed to elucidate these impacts. There are limited publicly available peer-reviewed, published studies on the safety of cannabis and cannabis-derived compounds particularly regarding use in food products or dietary supplements. Research is also needed to understand the effects of food products and dietary supplements containing cannabis and cannabis-derived compounds on vulnerable populations such as children, adolescents, pregnant and lactating women, particularly long-term effects. A 2017 National Academies of Sciences, Engineering and Medicine report “The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research” found that acute use of cannabis could impair learning, memory and attention span for users under the age of 16. However, it is important to note that this report focuses on published literature which relates primarily to recreational use of marijuana that is smoked, rather than edible cannabis and cannabis-derived compounds in food products. Little is also currently known about how cannabis and cannabis-derived compounds interact with other food ingredients or prescription and OTC drugs consumers may be using. It is important to capture future research findings related to health and safety effects of food products and dietary supplements that contain cannabis and cannabis-derived compounds in order to better inform FDA’s regulatory framework for these products.

Of concern to ASN is the potential for requirement of an Investigational New Drug (IND) application for future studies related to hemp and CBD (the non-psychoactive component of cannabis) in food products that will not result nor are intended to result in the development of drugs or drug claims. Once safety has been adequately assessed (beyond self-affirmed

GRAS status), exemptions should be permitted, and a waiver should be available for research related to food products containing CBD, as well as hemp and hemp-derived compounds. Such barriers to research, including Schedule I status and its resulting research restrictions for non-THC containing cannabis-derived compounds, are not conducive to understanding the health impacts and safety of cannabis and cannabis-derived compounds in food products and dietary supplements.

Perhaps because of its classification as a Schedule I substance, there is a scarcity of knowledge and a wealth of misinformation among consumers regarding hemp, cannabis and cannabis-derived compounds in food products and dietary supplements. This is also true among the health care and medical professional communities. Considerable consumer education needs to be provided regarding products that contain cannabis and cannabis-derived compounds, on topics such as health impact and proper use. Research is an important component to help us formulate credible education tools.

ASN commends the Agency's efforts to gain scientific data and information about products containing cannabis or cannabis-derived compounds to ensure consistency and safety of this rapidly expanding category of food products and dietary supplements. Clarity will help both industry and consumers make more informed choices regarding products containing cannabis and cannabis-derived compounds. Thank you for your consideration of ASN's comments. Please contact Sarah Ohlhorst, Senior Director of Advocacy and Science Policy [sohlhorst@nutrition.org; 240.428.3647], if ASN may provide additional information.

Sincerely,



Richard D. Mattes, PhD, MPH, RD
2019-2020 President, American Society for Nutrition