Mr. Schiller:

The Colorado Department of Agriculture (CDA) and the Colorado Department of Public Health and Environment (CDPHE) jointly thank you for the opportunity to comment on the Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds request from the Food and Drug Administration (FDA), published on April 3, 2019. Our primary purpose in submitting these comments is to underscore our strong belief that FDA’s regulatory framework toward hemp should afford flexibility and allow states such as Colorado to facilitate the development of a robust and thriving new industry. As we explain below, Colorado is a national leader in the emerging hemp industry. However, for the industry to reach its full potential, we feel it is important for FDA and other federal regulatory authorities to refrain from taking actions that may impede interstate commerce or otherwise discourage a new industry from establishing itself as an important economic driver in Colorado and throughout the United States.

In Colorado, hemp is a quickly emerging industry, and we are poised to lead the nation in the cultivation and production of hemp. The State of Colorado’s leadership in developing the hemp industry is demonstrated by a statewide initiative, led by CDA and CDPHE, to develop a framework to help the hemp industry thrive. We want hemp to operate on a level playing field, from cultivation to the processing and manufacturing of hemp products, including those consumer commodities that contain cannabidiol (“CBD”). Our agencies and some of our industry representatives participated in the FDA public hearing that was held on May 31, 2019, at the White Oak Campus. The State of Colorado is committed to working with our federal partners at FDA, USDA, and EPA to facilitate the development of a responsible, safe, and productive hemp industry in Colorado and throughout the United States.

The Agriculture Improvement Act (2018 Farm Bill) provides states with autonomy to establish plans to manage this emergent industry. In Colorado, we are developing a state-specific blueprint on how to manage the industry and ensure its sustainability by examining the entire supply chain from cultivation to market. Establishing this comprehensive framework will require a number of different State agencies’ involvement. To that end, CDA and CDPHE will be leading these efforts and will be partnering with leading state, local, and tribal agencies, as well as industry experts in the areas of cultivation, testing, research, processing, finance, and economics to establish this statewide blueprint known as the Colorado Hemp Advancement and Management Plan (CHAMP). Once developed, the CHAMP will outline each agency’s roles and responsibilities in the oversight and governance of hemp.
In keeping with CDA’s core mission to continuously strengthen and advance Colorado agriculture, a key objective of the CHAMP initiative will be to define a well-structured supply chain for hemp in order to establish a strong market for Colorado’s farming communities, while aligning with CDPHE’s mission to ensure that hemp-derived products advance Colorado’s health and protect the places we live, work, and play. We believe that the CHAMP initiative will serve not only as the blueprint for Colorado’s hemp industry but can serve as a model for other states, tribes, and territories.

**FDA: Human Food and Supplements**

Colorado agrees with FDA that hemp products cannot directly or indirectly infer the prevention, diagnosis, mitigation, treatment or cure of disease. However, as FDA navigates how to approach regulating this commodity, Colorado believes it is critically important that FDA not take any action that impedes or discourages the safe and responsible cultivation, sale, and transport of hemp or hemp-derived products. We are specifically concerned that FDA’s actions could discourage the sale of hemp-related products in interstate commerce and we respectfully request that FDA carefully consider the impact of its decisions on this important aspect of the industry before taking any regulatory action. At the same time, we fully support utilizing the federal requirements established in 21 CFR Part 117, “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food,” and 21 CFR Part 111, “Current Good Manufacturing Practice Regulations and Controls are Used for Manufacturing, Processing, Packing, or Holding Dietary Supplements.”

**EPA: Pesticide Tolerances**

Like any other plant grown for consumption or for sale, hemp cultivators experience pest pressures. As a result of these pest pressures, hemp growers commonly use pesticides to control or mitigate their pest problems in an effort to maintain high quality and maximize the productivity of their crops. Without a process in place to determine what registered pesticides are lawful to use, hemp growers and consumers are not being afforded the protections contemplated by the Food Quality Protection Act (FQPA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with regard to the efficacy and suitability of pesticides used on raw agricultural commodities intended for human consumption.

Additionally, the extraction of cannabinoids using solvents has been shown to concentrate not just the desired cannabinoids, but pesticides on the plant as well. This potential to concentrate pesticides is a risk that should be assessed by the EPA. However, EPA is not likely to undertake a risk assessment unless hemp can be considered a food as well as a drug.

Currently, there are very few pesticides available that identify hemp as an approved site for use and those we have identified are geared toward non-food industrial use. EPA is required to establish a tolerance for pesticides in food; however, there is no such obligation to establish a tolerance for pesticides used in the production of drugs. A concern in Colorado is that until hemp and its derivatives are considered a food or dietary supplement by FDA, EPA will not be under a legal obligation to consider the risks associated with pesticide use on hemp and will not require the full panel of risk assessments to establish pesticide tolerances.

Colorado has emerged as a national leader in the development and implementation of both recreational and medical marijuana programs, as well as a thriving hemp program. These programs have provided us with an opportunity to learn lessons about how to effectively regulate cannabis from the grow site to the consumer that ensures security and truthful representation of the commodity
while ensuring public safety. Despite the fact that both commodities are derived from the cannabis plant, Colorado has kept the regulation and administration of hemp separate from marijuana. We are heartened to know that the USDA, FDA, and EPA will provide us with the space to develop a system that works for Colorado.

In partnership

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