CCSS
The Collaborative for CBD Science & Safety

VIA ELECTRONIC DELIVERY

Monday, January 11, 2021

Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237

RE: Collaborative for CBD Science and Safety (CCSS) Comments on New York Proposed Regulations for Cannabinoid Hemp Products

Dear Members of the New York State Department of Health:

On behalf of the Collaborative for CBD Science and Safety (CCSS), we are writing today in response to the recently released *Proposed Regulations for Cannabinoid Hemp Products* and associated public comment period.

The CCSS is an informal organization of stakeholders throughout the healthcare delivery system and supply chain who have come together to exchange information, build alliances around shared interests and priorities, and respond to policies and practices affecting cannabidiol (CBD) availability, research, safety, and quality.

Over the course of the last several months, New York State lawmakers and regulators have made significant strides to promote more stringent licensing requirements for processors and sellers as well as set quality controls driven by consumer health and safety concerns. We applaud Governor Cuomo and other state leaders for their well-intentioned efforts to address a growing market that has gone largely underregulated at the expense of the consumer.

We share a common goal in driving towards a safe and sustainable marketplace, however, wish to raise certain components of the proposed cannabinoid hemp regulation that may adversely affect consumer health and safety. This is particularly important given the prevalence of fraud and misinformation occurring related to the use of CBD to treat or mitigate COVID-19. To date, 13 warning letters have been issued to individuals and organizations claiming the therapeutic benefit of CBD during the pandemic.

Embedded within our organization's name is our commitment to rigorous science. We believe that decision-making throughout the cannabis and hemp industry, focused primarily on the development and commercialization of cannabidiol, must rely upon evidence-based scientific standards and best practices that promote the availability of safe, high-quality consumer products. Equally important is the development of a regulatory framework that ensures clarity and consistency for product development and manufacture for industry, healthcare providers, and consumers alike.

To that end, the CCSS believes it is the responsibility of the Food and Drug Administration (FDA) to develop and promulgate national standards for safe cannabidiol (CBD) daily intake limits in foods and dietary supplements (including threshold limits per package). We urge the New York State Department of Health to follow the limits set by FDA rather than the state itself. State efforts to establish independent threshold limits per package create a regulatory patchwork that poses risks to public health. It is squarely within FDA's jurisdiction to set these limits and establish a national standard to protect all Americans.

Specifically, Section 1005.8(b) seeks to set maximum product thresholds for cannabinoid content in foods and dietary supplements at 25mg and 3,000mg, respectively. However, because the proposed regulation fails to impose any restrictions on the size of individual servings for dietary supplements or on the permissible concentration of CBD, a threshold of 3,000mg per product would permit such products to meet or exceed the CBD concentration of currently available, FDA-approved prescription drugs. For example, a dietary supplement of a common vial size—30 milliliters—could contain 100mg/ml of CBD, the same CBD concentration as Epidiolex, the only FDA-approved, prescription-strength CBD. Further, pursuant to the regulation, a 20 milliliter bottle could potentially contain 150mg/ml of CBD, which exceeds the current prescription strength. At 3,000mg per product package, and without an associated threshold for daily intake, the proposed regulation would therefore permit potent and concentrated daily servings that may cause adverse health effects. This is concerning as it undermines FDA's prescription drug regulatory authority, could result in harmful health and safety impacts, and disincentivizes the development of new CBD-containing prescription medicines.

Further consumer health and safety concerns may arise in subsequent interpretation of Section 1005.8(a)(6) around ensuring accurate concentration limits. At the current levels proposed, a 10% deviation in either direction could have significant impacts on consumers. We strongly believe that federal regulators at the FDA should set national standards for CBD and other cannabinoid intake limits, particularly for consumer-grade products where such thresholds may result in already demonstrated liver injury or other drug-drug or drug-supplement interactions.

Thank you for the opportunity to submit comments on this important public health and consumer safety issue. The Collaborative for CBD Science and Safety [or undersigned organizations] remain available to you and your colleagues as a resource and appreciate your consideration of this content. Please visit www.CBD-Collaborative.org for more information.

Respectfully,

The Collaborative for CBD Science and Safety