December 23, 2020

Via Electronic Communication

Katherine Ceroalo
Department of Health
Bureau of Program Counsel
Reg. Affairs Unit, Room 2438
Empire State Plaza Tower Building
Albany, NY 12237
regsqna@health.ny.gov

Re: Opposition in Part to HLT-45-20-00002-P

Dear Ms. Ceroalo:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to participate in this rulemaking and that New York is establishing important consumer protection standards for the retail cannabinoid hemp industry. Manufacturing standards, product labeling, and quality assurance testing requirements will reduce some risks associated with the consumption of hemp-derived products, such as cannabidiol (CBD). However, we are writing to express concern about proposed 10 NYCRR § 1005.8, which would allow high levels of CBD concentration in food and dietary supplements, as it conflicts with federal law and may pose risks to consumers. Namely, we are concerned that this regulation (1) conflicts with the Food, Drug, and Cosmetics Act (FDCA), and therefore, allows the sale of products that the U.S. Food and Drug Administration (FDA) has deemed to be illegal; and (2) allows for concentration levels that may pose serious health concerns for consumers.

A. Conflicts with Federal Law

We are concerned that § 1005.8 would permit the sale of products that are illegal under the FDCA. Under that law, if an article such as CBD has been studied as a drug or approved as a drug by the FDA prior to that article being marketed in a dietary supplement or as an ingredient in food, no food or dietary supplement may contain that same active ingredient.[1] In this case, CBD was studied as a drug as early as 2006,[2] and the FDA approved a prescription drug containing CBD as an active ingredient in June 2018.[3] All other CBD products at that point were still considered

[1] 21 U.S.C. §§ 321, 331. In particular, §321(ff) excludes drugs from the definition of dietary supplements, while § 321(ll)(3)(C) prohibits the addition of drugs to food as they are not GRAS or an approved additive. 21 U.S.C. § 321.
[2] https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd
[3] *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, U.S. FOOD & DRUG ADMIN. (June 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms#:~:text=The%20U.S.%20Food%20and%20Drug,years%20of%20age%20and%20older.

schedule I substances (i.e., illicit substances) under the federal Controlled Substances Act (CSA).[4] Congress did not attempt to legalize hemp-derived CBD under the CSA until December 20, 2018 when it passed the Agriculture Improvement Act of 2018 (Farm Bill).[5] At that point, the Farm Bill removed "hemp," including hemp-derived CBD, from the CSA's definition of marijuana and the schedule I listing of THC.[6] However, given that CBD was already studied and approved as a drug before the enactment of the Farm Bill, any food or dietary supplement product containing CBD are still prohibited under the FDCA. As a result, the FDA has stated that it is illegal to market non-FDA-approved CBD products by adding them to food or labeling it as a dietary supplement.[7] Therefore, § 1005.8 would allow the sale of products that are prohibited under federal law. The FDA is currently exploring potential regulatory pathways for CBD products to be lawfully marketed.[8]

B. Health and Safety Risks

Aimed Alliance is concerned that high concentrations of CBD per product, as permitted by § 1005.8(b), may present serious health and safety risks for consumers. Section 1005.8(b) allows for a maximum of 25 milligrams of total CBD per food or beverage product and 3,000 milligrams of total CBD per dietary supplement product. Yet, rigorous scientific data on CBD's safety and efficacy, including data on appropriate dosing, is currently lacking. The FDA has stated that there is "only limited data about CBD safety and these data point to real risks that need to be considered before taking CBD for any reason."[9] In particular, the FDA points out that CBD use may result in liver injury, negative effects from interactions with other drugs, male reproductive toxicity,

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[4] *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, U.S. FOOD & DRUG ADMIN. (June 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms#:~:text=The%20U.S.%20Food%20and%20Drug,years%20of%20age%20and%20older.

[5] Agriculture Improvement Act of 2018, Pub. L. No. 115-334, available at https://www.congress.gov/bill/115th-congress/house-bill/2.

[6] RENÉE JOHNSON, CONG. RESEARCH SERV., R44742, DEFINING HEMP: A FACT SHEET 4 (Updated 2019), available at https://fas.org/sgp/crs/misc/R44742.pdf.

[7] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis#:~:text=The%20FDA%20has%20approved%20only,it%20as%20a%20dietary%20supplement (last updated Mar. 5, 2020). But note that the FDA considers certain foods containing hemp and hemp seed-derived food ingredients to be "generally recognized as safe" or GRAS. *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food*, U.S. FOOD & DRUG ADMIN. (Dec. 20, 2018), https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.

[8] *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Advance Agency's Continued Evaluation of Potential Regulatory Pathways for Cannabis-Containing and Cannabis-Derived Products*, U.S. FOOD & DRUG ADMIN. (April 2, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation.

[9] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis#:~:text=The%20FDA%20has%20approved%20only,it%20as%20a%20dietary%20supplement (last updated Mar. 5, 2020).

gastrointestinal distress, changed in mood, potential cumulative effects, and unknown risks arising in special populations, like the elderly, children, and pregnant and lactating women.[10]

When a product contains high concentrations of CBD, there is a serious risk that consumers will consume more than the recommended dose of CBD products, potentially placing them at risk for experiencing these adverse events. Popular food products containing CBD include gummy candies, cookies, and treats, some of which may be tempting to young children. While a serving size may be one gummy or one cookie, a consumer may consume the entire package or consume CBD from a variety of different sources throughout the day, thereby increasing their risk of adverse effects.

Supplements with as much as 3,000 mg per product can result in adverse events. Popular CBD products marketed as dietary supplements include oils and tinctures. Oftentimes, it is hard to measure correct doses, which may be a single drop from a pipette. Additionally, when consumers do not immediately feel any effects, they often take several subsequent servings. Moreover, the concentration levels permitted by the proposed rule are higher than those contained in the FDA-approved CBD product and in most existing CBD products marketed as dietary supplements. The 3,000 mg limit included in the proposed rule will result in products sold with high daily servings of CBD. Such high CBD concentrations in daily servings risk negative health effects for consumers who use CBD regularly, including liver injury, negative drug interactions and potential male reproductive toxicity.

This issue is also compounded by frequent mislabeling of CBD products, which may result in consumers consuming larger amounts of CBD than intended.[11] Even if labels accurately reflect the concentration present in the bottle, consumers are often confused regarding CBD dosages, leading to both higher or lower consumption rates than intended.[12] This confusion may lead to accidental consumption of high levels of CBD contained in dietary supplements, far in excess of the FDA's recommended dose for medical purposes, placing consumers at risk of health risks.[13]

Furthermore, because non-FDA-approved CBD products do not have to go through the rigorous safety and efficacy protocols or meet standards for quality, purity, and dosage, products may be adulterated with harmful substances, including high levels of THC, heavy metals, toxins, and mold. The FDA demonstrated this in its July 2020 study, which found that nearly 50 percent of

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[10] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis#:~:text=The%20FDA%20has%20approved%20only,it%20as%20a%20dietary%20supplement (last updated Mar. 5, 2020).

[11] U.S. FOOD & DRUG ADMIN., REPORT TO THE U.S. HOUSE COMMITTEE ON APPROPRIATIONS AND THE U.S. SENATE COMMITTEE ON APPROPRIATIONS: SAMPLING STUDY OF THE CURRENT CANNABIDIOL MARKETPLACE TO DETERMINE THE EXTENT THAT PRODUCTS ARE MISLABELED OR ADULTERATED (2020), available at https://www.akingump.com/a/web/mrPFoXtgPYvzSxv9hd2fKq/cbd-marketplace-sampling_rtc_fy20_final.pdf.

[12] Edwina Billhimer, *The CBD Products Lie*, MEDIUM (Mar. 28, 2019), available at https://medium.com/@ediebillhimercaito/the-cbd-products-lie-f378222bb9cd (anecdotal evidence of consumer confusion).

[13] *Epidiolex Label*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf (last visited Dec. 22, 2020).

the tested CBD products had THC levels above the Limit of Quantification.[14] CBD products that have THC levels in excess of the Limit of Quantification fall under the purview of the Controlled Substances Act (CSA), and remain illegal under federal law.[15] Although we hope that New York's testing requirements prevent adulteration in CBD products, we remain concerned that the levels of concentration allowed in this proposed rule may result in additional complications due to increased usage and cumulative effects that have not yet been determined. As a result, concentration levels for CBD food and dietary supplements should be determined by the FDA to ensure consumer safety.

In conclusion, to prevent conflicts with federal law and to ensure patient health and safety, we encourage the New York Department of Health to prohibit the marketing and sales of CBD in food and dietary supplements until the FDA has released a regulatory pathway for such products. In the alternative, if New York continues to allow such products to be marketed in the state, we recommend that the Department of Health wait until the FDA has released its regulatory pathway to determine concentration levels for CBD products. Please contact us at policy@aimedalliance.org if you have any questions.

Sincerely,

Stacey L. Worthy
Counsel

[14] U.S. FOOD & DRUG ADMIN., REPORT TO THE U.S. HOUSE COMMITTEE ON APPROPRIATIONS AND THE U.S. SENATE COMMITTEE ON APPROPRIATIONS: SAMPLING STUDY OF THE CURRENT CANNABIDIOL MARKETPLACE TO DETERMINE THE EXTENT THAT PRODUCTS ARE MISLABELED OR ADULTERATED, (2020), available at https://www.akingump.com/a/web/mrPFoXtgPYvzSxv9hd2fKq/cbd-marketplace-sampling_rtc_fy20_final.pdf.

[15] *See* Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639, 51640 (Aug. 21, 2020) (interim final rule).