Subject: Sale of CBD Supplements Violates DSA Code of Ethics: Code Administrator Advisory

As you know, this office has been given the responsibility by the DSA Board of Directors to oversee the compliance of DSA members with the association's Code of Ethics. Compliance with the DSA Code is a condition of membership, to which all DSA members have agreed upon joining the association and which has been a requirement over the past 45 years. This memorandum is to make you aware of the legal issues raised by the sale of CBD (cannabidiol-based oils) ingestible products as it relates to the DSA Code. Based on review of the publically available resources, including the U.S. Food and Drug Administration (FDA), it is **the determination by this office that sale of ingestible CBD products such as a foodstuff, nutritional supplement, tinctures, or for any digestible means for humans or animals is violative of the DSA Code of Ethics.**

Numerous recent news articles and CBD-product promotional materials have cited the passage of the 2018 Farm Bill as permitting, under federal law, the sale of hemp-based products such as CBD oil. While that legislation may have impacted the legality of non-ingestible CBD-containing products such as creams and lotions, this memorandum does not seek to address those products nor the federal or state laws that may cover such sales.

As DSA members that market nutritional and related products know, federal law generally does not regulate the sale of nutritional supplements as long as those products do not make unsubstantiated claims and/or claims to cure disease or similar medicinal benefits. However not all "supplements" qualify for this regulatory exclusion. The exclusionary clauses of the Federal Food, Drug, and Cosmetic Act provide that a substance approved as a new drug or the subject of substantial clinical investigations which have been made public **is prohibited from use in food or dietary supplements unless the substance was first marketed as a food or dietary supplement.** To this point, the Food and Drug Administration has approved CBD as an active ingredient in an epilepsy drug, Epidiolex and CBD is currently the subject of substantial clinical investigations which have been made public. FDA has also stated that the "first marketed as" exemption to the exclusionary clauses does not apply to CBD, as the agency is not aware of any data demonstrating that CBD was marketed as a food or dietary supplement prior to the initiation of substantial clinical investigations of CBD as a drug.

This statement below by then FDA Commissioner Scott Gottlieb, M.D. on December 19, 2018 points out that the agency considers ingestible CBD as a drug because of its prior approval for inclusion in the above-mentioned epilepsy medication:

> *Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements.* ***Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.*** *(*emphasis added)

In addition, not only did Dr. Gottlieb make a categorical statement as to this effect late last year but also on June 16 of this year the FDA stated *"... We are aware that there may be some products on the market that add CBD to a food or label CBD as a dietary supplement.* ***Under federal law, it is currently illegal to market CBD this way."*** (emphasis added)(https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd)

Recognizing the need for additional information regarding the use of CBD-based products and the FDA's role in regulation of such products, the agency held a daylong hearing on May 31, 2019 to permit public testimony. Presenters at that hearing included academics, medical professionals, researchers, manufacturers, and consumers of various CBD products. Questions raised by FDA staff and witnesses at the May 31 hearing included drug interaction, dosage limits, impacts of long-term usage, purity of contents, and use of CBD products by the very young should be of concern to any trade association whose members sell these products.

It is important also to note that there was sufficient interest in this topic within DSA that the association held a dedicated panel discussion about CBD-based products at the June Annual Meeting. The CBD panel discussion during that meeting revealed no present information that would counter the conclusion that the sale of CBD-infused ingestible products is prohibited by federal law.

While the FDA concedes it has not yet determined the appropriate path to take in regulating the increasing use of CBD-infused supplements, **the fact that the FDA may not be enforcing the law as it exists does not nullify the facts nor vitiate the application of the Code.** Section A.1.b. of the DSA Code of Ethics states:

> *Member companies and their independent sales people must comply with all requirements of law. …**Compliance with all pertinent laws by member companies and their independent sales people is a condition of acceptance by and continuing membership in DSA***. (emphasis added)

In conclusion, public statements by FDA officials together with the disclosures made during the agency's hearing discussed above as well as DSA's panel discussion at the Annual Meeting confirm that the present sale of ingestible CBD products is illegal under federal law and hence violates the DSA Code of Ethics.

This office is well aware and appreciates the fact that the legal status of CBD ingestible products may be in flux as the FDA considers its options in regulating these products. See https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer. Consequently, for the next 90 days, DSA companies presently selling CBD-infused ingestible products will not be cited for DSA Code of Ethics violations for that sale. This 90-day window will account for additional time to permit the FDA to articulate a path forward wherein sale of these products may be deemed legal. If the FDA does not act within that timeframe, and CBD-infused products continue to be sold in interstate commerce by a DSA member, that company may be deemed to be in violation of the DSA Code of Ethics. The company will be requested to remedy this Code violation by halting sales of those products. If after that final notice the DSA member company is in violation of the DSA Code of Ethics, and CBD-ingestible sales continue to occur, the Code requires this office to notify the DSA Board of Directors of the member's ongoing violation of the DSA Code of Ethics by such sale.

Sincerely,

Jared O. Blum
DSA Code Administrator