



March 11, 2019

Mr. Andrew Hatch
Chief, Program Services Branch
Marketing Order and Agreement Division, Specialty Crops Program
Agricultural Marketing Service, United States Department of Agriculture
1400 Independence Ave. SW
Washington, D.C. 20250

Dear Mr. Hatch:

On behalf of the American Veterinary Medical Association (AVMA) and our member veterinarians, we thank you for the opportunity to provide comments as the U.S. Department of Agriculture (USDA) prepares to implement the Agriculture Improvement Act of 2018 and engage in rulemaking to regulate hemp production.

The AVMA appreciates USDA's outreach to stakeholders as the Agricultural Marketing Service works to develop and implement a nationwide program for overseeing the production of hemp. Amongst the diverse hemp products that may result from such programs, veterinarians have an interest in the production and uses of cannabinoid products. We receive countless reports from our members indicating that animal owners are actively purchasing these products and administering them to their pets and horses to treat medical conditions in the absence of veterinary consultation. We are also aware of several research institutions with both completed and ongoing investigations into the potential therapeutic benefits of cannabinoids for animals. Indeed, with the Food and Drug Administration's stated awareness of growing public interest in cannabis and cannabis-derived products, and intent to gather stakeholder input regarding these products, their safety, and potential pathways for an efficient regulatory framework, there is much to indicate that cannabis and cannabis-derived compounds and products will continue to be of interest to the veterinary community, our patients, and our clients.

To help ensure the quality of such products, AVMA encourages the USDA to consider how standards for production of hemp (and hemp-derived products) will ultimately support the efforts of the Food and Drug Administration (FDA) to establish a regulatory pathway that preserves the opportunity for some products to be brought to market as pharmaceuticals, while allowing others to potentially be brought to market as food additives. The regulatory structure required to address both routes to market is likely to be complex. Given this anticipated complexity, it is imperative that guidance from USDA be carefully developed and clearly communicated. As there is potential for a multitude of state programs to rely on the parameters set forth by USDA, the future ability of the federal government to effectively regulate these products as pharmaceuticals, food additives, or in other forms will depend on uniform sampling and testing during production.

Therefore, we encourage USDA to establish a uniform standard, acceptable sampling and testing methods, and acceptable processing methods, with respect to all aspects of hemp production, but particularly regarding determination of the concentration of delta-9-tetrahydrocannabinol (THC) within

hemp plants, seeds, and their derivatives. An accurate way to determine THC content in varying types of product (e.g., plant, seeds, derivatives) is required to ensure the commodity produced, marketed, and sold meets the legal definition of “hemp” in the Agriculture Improvement Act of 2018. We recognize that accurately determining whether a plant and its derivatives meet the definition of “hemp” can be challenging because, depending on which portion or part of a plant or derivative is sampled, and what analytical method is used, varying THC concentrations may result. Uniform standards for field sampling and testing of THC content are needed so that producers and their customers may have confidence they are meeting requirements set by the Act for this commodity.

Because the AVMA is a scientific organization that relies on evidenced-based medicine, we support further research on cannabis-derived products as therapeutics, so that FDA approval of such products may be obtained. Such approval provides the assurance we need that products made available for use in veterinary patients are efficacious and safe. Ultimately, we hope that the collaborative efforts of the USDA and FDA with respect to hemp and its products will result in improved health and wellbeing for our patients.

Thank you again for the opportunity to provide feedback on the proposed revisions. We appreciate your consideration of our concerns and requests and look forward to continued collaboration with the USDA and FDA. If you have further questions or would like more information, please contact Dr. Gail Golab, Chief Veterinary Officer, at 847-285-6618 or via e-mail to ggolab@avma.org; Dr. Dharati Szymanski, Assistant Director, Division of Animal and Public Health, at (847) 285-6742 or via e-mail to dszymanski@avma.org; or Dr. Lauren Stump at (202) 289-3211 or via email to lstump@avma.org.

Sincerely,

A handwritten signature in black ink that reads "Janet D. Donlin DVM". The signature is written in a cursive, flowing style.

Janet D. Donlin, DVM, CAE
Executive Vice President

DS/LS/GCG/ML