Cannabis and Cannabis Derivatives, Including CBD: A Regulatory Update for Veterinarians

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Abbreviations

AAFCO	Association of American Feed Control Officials
CBD	Cannabidiol
CGMP	Current Good Manufacturing Practice
CVM	Center for Veterinary Medicine
FD&C Act	Food, Drug, and Cosmetic Act
NAERS®	NASC Adverse Event Reporting System
NASC	National Animal Supplement Council
Q	Quarter
THC	Tetrahydrocannabinol

Abstract

This article offers an update on the current regulatory status of cannabis and cannabis derivatives, including cannabidiol (CBD), and provides an overview of regulations created by the Agricultural Improvement Act of 2018 and the resulting impact on products containing these substances. Additionally, the article addresses steps being taken toward the approval of cannabis and cannabis derivatives in animal food/feed for nutritional benefits and the status of products containing cannabis and cannabis derivatives, including CBD, for non-nutritional health benefits. The article outlines what veterinarians should be aware of when discussing these products with clients and considerations for veterinarians who recommend or dispense a product containing these components. The article concludes with information on how veterinarians can identify responsible suppliers in this product space and avoid "bad actors" that are harming the segment and the industry.

Introduction

As the leading trade association in the world representing companies that manufacture and sell products similar to dietary supplements but marketed for dogs, cats, and horses, the National Animal Supplement Council (NASC) has had the issue of cannabis and cannabis derivatives, including cannabidiol (CBD), on its radar for nearly 3 years. As president of NASC, the author has spoken extensively on this topic and has worked closely with regulators, industry (both animal and human), leading law firms, and other stakeholders to responsibly address the use of cannabis and cannabis derivatives in animal health products and animal feed, which includes animal treats. NASC believes it is important to provide clarity and information to veterinarians interested in the use of cannabis products in their practices so they will have a more complete understanding of the current regulatory landscape.

Federal and state laws around cannabis and cannabis derivatives are complex, with the regulatory landscape constantly evolving. What is printed here was true and correct at the time of writing; however, regulatory changes may have taken place by the time this article is published, and it is wise to reference the NASC website for the most recent developments and updates (1).

It is worthwhile to mention that the regulatory requirements that exist for human dietary supplements and cannabis products are not the same as the regulatory requirements for animal products. The US Congress (Congress) passed the Dietary Supplement Health Education Act (DSHEA), which was signed into law in October 1994 and modified the Federal Food, Drug, and Cosmetic Act (FD&C Act), creating a category for human dietary supplement products as a subset of human food. In April 1996, the FDA's Center for Veterinary Medicine (CVM) published an opinion in the *Federal Register* stating that Congress did not intend for DSHEA to apply to similar products for animals (2). Consequently, there are only 2 categories available under current law for these types of animal products: animal food/feed and animal drugs. All "supplements," including cannabis products, are classified as food or drugs based first on the intended use, with ingredients and delivery form also being a consideration. The definitions in the FD&C Act can be viewed on the US House of Representatives US Code website (3).

Terminology and Current Legal Status

CBD is one of many cannabinoids, terpenes, and other components found in the hemp and marijuana plant, specifically *Cannabis sativa* L. The Agricultural Improvement Act of 2018, also known as the 2018 Farm Bill, federally defined hemp as *Cannabis sativa* L. containing less than 0.3% delta-9 tetrahydrocannabinol (THC) on a dry weight basis. Marijuana is defined as *Cannabis sativa* L. containing THC equal to or greater than 0.3% on a dry weight basis. The Farm Bill made hemp legal as an agricultural crop, subject to both state and federal regulations, and further defined hemp as "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis" (4).

It is important to understand the definition of hemp because the highest concentrations of cannabinoids, including CBD, are contained in the flowering tops and resins of the plant. Hemp seeds, which are a potential good source of omega 3 and 6 fatty acids, are now allowed to be utilized as a separate component of the whole hemp plant. Additionally, the Farm Bill specifically allows any part of the plant to be used.

The Farm Bill, however, did not make articles of commerce (meaning products) containing these substances legal. Only the drug EPIDIOLEX®, which the FDA granted permission to be marketed on June 25, 2018, can be marketed legally.

The Farm Bill did remove the U.S. Drug Enforcement Administration (DEA) from involvement and removed the classification of hemp from Schedule I of the Controlled Substances Act, provided the THC concentration meets the requirement of less than 0.3% on a dry weight basis. The Farm Bill also assigned the responsibility for developing a framework for registration and regulatory oversight to the states and Indian tribes.

This, of course, raises questions about who regulates products containing cannabis or cannabis derivatives and why these products are so readily available in the marketplace if they are not legal. The CVM has ultimate regulatory authority over an article of commerce — for example, a product marketed for animals. On the human side, food, dietary supplements, and drugs are also regulated by the FDA. However, on the animal side, products are also potentially regulated at the state level as either an animal food/feed (nutritional product) or an animal remedy/drug product. Animal feed is regulated by state departments of agriculture or other state agencies with regulatory oversight, which may be affiliated with the state chemist's office or a state university, for example, the Office of the Texas State Chemist, the Office of the Indiana State Chemist–Purdue University, or University of Kentucky–Division of Regulatory Services.

Some states have animal remedy laws for both companion animals and livestock. These states are Texas, Oregon, North Dakota, South Dakota, the Commonwealth of Virginia, and California; however, California state law administered by the California Department of Food and Agriculture only covers livestock remedies.

The Association of American Feed Control Officials (AAFCO) is a nonprofit association that recommends

regulatory policy for animal food. Although AAFCO has no regulatory authority, the association does have a very close working relationship with the CVM. Most states are represented at AAFCO meetings and follow the association's model pet food bills and regulations recommended in the AAFCO Official Publication (5).

The CVM has indicated that they will follow the guidance from the human side and that the agency wants to speak with one voice, especially on the topic of cannabis and cannabis derivatives. The FDA has been consistent in their position that cannabis and cannabis derivatives such as CBD may not be added to food or dietary supplements due to the substance being approved as a drug (6). Unfortunately, despite this being the position repeatedly articulated by the agency, enforcement action has been sporadic at best, and this can also be said for animal products either nationally by the FDA or at the state levels. The FDA did act in early 2015 by issuing numerous warning letters to companies that were promoting products as beneficial for treating chronic conditions, such as arthritis, cancer, and chronic pain (7).

In summary, the bottom line is that, despite the current position of the FDA that cannabis and cannabis derivatives, including CBD, are not approved for use in human products, enforcement action has not been taken to any great degree. This fact, combined with many states approving marijuana for both medicinal and recreational use, has led to unforeseen consumer demand for these products, especially CBD products. The animal industry is a "fast follow" industry, and this is certainly the case with CBD products and treats for animals despite the position of the CVM, AAFCO, and the states that these substances are not approved for use in animal feed, and enforcement action has been sporadic at best (8). The regulators, veterinary medical associations, responsible members of the industry, and other stakeholders will have to find pathways to responsibly deal with the issue of products containing hemp and CBD for both humans and animals.

FDA Seeks Clarity

The FDA realizes this issue is extremely important to the public, and most stakeholders believe the agency is looking for a workable solution. The lightning speed with which these products took off in both the human and animal industries took most of the regulatory agencies by surprise, and in retrospect it would have been ideal had they acted sooner. That said, in response to the demand for products, the FDA held a public hearing on May 31, 2019, to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. Thousands applied to give testimony, and NASC was among the 140 selected to testify before the FDA panel, which also included representatives from the CVM. A complete transcript of the testimony given by those who testified is available online (9).

Written comments (see **Appendix** page 33) accompanied the author's verbal testimony, given on behalf of NASC members and the animal industry, as well as data from the NASC Adverse Event Reporting System (NAERS®) that was referenced in the testimony. NASC has since provided the FDA with an updated NAERS® Ingredient Risk Report (**Figure 1**) at the agency's request.

Following verbal testimony, the FDA panel had the opportunity to ask questions of each speaker, including the following:

• Does NASC have data to back the statement that the organization fully supports the 0.3% THC threshold? The author affirmed that NASC does have data.

• What does NASC see as the intended use of cannabis or cannabis-derived compounds? The author responded that NASC is consistent with section 201(g)(1)(c) of the FD&C Act — non-nutritional benefits, occasional discomfort, cognitive function, immune support, and similar structure and function examples.

• Does NASC also have data on swine or bovine? The author clarified that NASC's focus is on dogs, cats, and horses only, not production animals.

• Was the safety database reporting mentioned in the author's testimony mandatory or voluntary? The author

National Animal Supplement Council

NASC INGREDIENT RISK REPORT

REPORT DATA GENERATED ON: 09/13/2019 12:25 pm

INGREDIENT INFORMATION

Ingredient name: Hemp and hemp-derived compounds

No. of NASC registered products with this ingredient: 231

Years ingredient on the market: 10 year(s)

Total:

Year	Adverse Events (AEs) Reported	Report Rate Per Million Administrations Sold	Serious AEs Reported	Report Rate Per Serious AE Per Million	Administrations Sold*
2010	0	0.00	0	0.00	25,016
2011	0	0.00	0	0.00	70,558
2012	0	0.00	0	0.00	200,351
2013	2	5.48	0	0.00	365,066
2014	0	0.00	0	0.00	679,401
2015	0	0.00	0	0.00	1,055,400
2016	0	0.00	0	0.00	1,857,242
2017	1	0.15	0	0.00	6,593,407
2018	4	0.23	0	0.00	17,487,861
2019	4	0.23	0	0.00	17,511,676
Grand total	11	0.24	0	0.00	45,845,979

The requirement for NASC members to enter AE reports began Q3 of 2003. Some companies were recording AEs prior to that time, and those data are displayed. NASC did not require reporting the number of administrations sold until Q3 2003, so data prior to that time are likely understated. Because we cannot be sure that the data prior to Q3 2003 are complete, we do not report AE incidence prior to that time. Please direct questions about NAERS and methodology to Bill Bookout at NASC, (760) 751-3360.

*Administrations sold is believed to be a close approximation to administrations consumed. Unlike human medicines, supplement bottles are generally consumed in their entirety unless there is an adverse reaction, the animal starts refusing it, or the animal dies. The administrations sold data do include increased amounts of product carried in the distribution channel. However, with increasingly efficient supply chain management, it is believed that changes in the total product in the channel is a negligible factor over time.

Adverse Event: An Adverse Event is a type of complaint where a patient has suffered any negative physical or health problem that may be connected to or associate with use of the product.

Serious Adverse Event: An Adverse Event with a transient incapacitating effect (i.e. rendering the animal unable to function normally for even a short period of time, such as with a seizure) or non-transient (i.e. permanent) health effect. Transient vomiting and/or diarrhea do not constitute Serious Adverse Events. A purported Serious Adverse Event requires follow-up with a veterinarian. A layperson diagnosis does not constitute a Serious Adverse Event.

Figure 1: Excerpt from an NASC NAERS® Ingredient Risk Report, generated on September 13, 2019, at the request of FDA, which shows 231 NASC registered products containing hemp and hemp-derived compounds, some of which have been on the market for 10 years. In those 10 years, 11 adverse events have been reported — none serious — in more than 45 million administrations of products containing hemp and hemp-derived compounds in dogs, cats, and horses.

clarified that NASC members commit to required reporting as a condition of membership. In addition, NASC has made the information available to the CVM, conducted training sessions with the CVM's Division of Surveillance, and continues to work closely with the agency.

The NAERS® is the most advanced database in the world for these types of products, and NASC tracks more than 6,500 products containing more than 1,400 unique ingredients, essentially in real time. Do these data substantiate safety? No. However, they do give a very clear indication of the risk of use, which is low, and are consistent with regulators' risk-based approaches to maintaining continued vigilance. These data, which protect the products that veterinarians and millions of animals depend on, come from NASC member companies and are a mandatory requirement for membership. When the author states that NASC member companies contribute to a cause greater than their own individual companies' self-interests, this is part of the context upon which that statement is based.

NASC's Position on Cannabis and Cannabis Derivatives

Consistent with the positions of the FDA, state regulators, and AAFCO, NASC supports the position that cannabis and cannabis derivatives, including CBD, are not approved or appropriate for use in animal food. Having said that, hemp and hemp seeds do hold great promise as viable sources of protein and fiber and as omega contributors for various animal species. There are groups working on these approvals, and NASC is highly involved in many efforts for dogs, cats, and horses and peripherally supporting livestock uses.

NASC does allow the use of cannabis and CBD in products for non-nutritional purposes, provided the company acts responsibly. As indicated in testimony to the FDA, NASC has created guidelines that are currently in effect for product production, testing, labeling, and monitoring. NASC met with the FDA in the 4th quarter (Q4) of 2019 to present the association's pathway forward, which will be required until the agency issues more clarifying guidance.

On the nutritional side, it is expected that hemp seed oil will be approved for use as a source of omega 3 and 6 fatty acids in dogs and cats by Q1 or Q2 2020. Other uses for hemp meal, hemp cake, or other applications will take longer and will be very expensive. Substantiating all that is necessary for production, testing, nutritional benefits, and safety takes considerable time and money, and it is estimated the time frame will be 2 to 3 years and will cost between $1.2 million and $1.5 million for each species.

It is doubtful that CBD for nutritional benefits will ever be approved, and in the time NASC has been involved in the CBD discussion, no data have surfaced supporting the nutritional benefits of CBD. Without any data to support this intended use, CBD will not be approved for nutritional benefits.

Where Does This Leave Veterinarians?

In addition to the regulatory agencies' various stances on products containing cannabis and cannabis derivatives, veterinarians need to be aware of the positions taken by the state veterinary medical association(s) in the state(s) where they practice as well as the position of the American Veterinary Medical Association (AVMA), which can be viewed online (10). In addition, it is wise for veterinarians to note discussions about CBD in patient charts and to document informed consent as an element of good recordkeeping. Veterinarians with questions about administration or protocols should seek advice from an expert.

Although some states do not object to veterinarians recommending and/or dispensing CBD products, others such as California currently allow veterinarians to discuss but not dispense. It should be noted that some states do not allow veterinarians to even discuss CBD and its use in their patients. Regardless of what a state allows, demand for CBD is not going away, and if clients cannot get input or product recommendations from the practitioner, they will seek it from another source — most likely the internet or a local retailer. NASC strongly supports veterinarians being allowed to discuss CBD and dispense quality products because it helps to prevent pet owners from selecting low-quality products from opportunistic suppliers

and potentially harming the animals they intended to protect.

The CBD product landscape is something of a "gold rush" and essentially has 3 types of companies offering products in the space: (1) NASC member companies that are committed to doing the right thing and are in favor of proactively establishing a responsible pathway forward; (2) companies that are not NASC members but are committed to acting responsibly; and (3) irresponsible companies that make mistakes but correct the issues when they are made aware, which effectively moves them to 1 or 2 above, and know they are making mistakes but don't care and have no intention of correcting the course. These companies are a threat to the industry, the products, and a segment of the profession seeking to establish credibility and recognition of beneficial integrative modalities.

The unfortunate reality is there are a few bad actors in the CBD space who are not veterinarians but are recommending "treatment protocols" for arthritis, seizures, cancer, dermatitis, and other chronic diseases and advising owners on the dosing of CBD products. This could equate to practicing veterinary medicine without a license, and unfortunately there is little accountability for these actions at this time. The companies are being allowed to exhibit at trade shows without any vetting of their claims, which only harms the companies that are trying to do business the right way and follow the rules. FDA warning letters, such as the one sent to Curaleaf, Inc., on July 22, 2019, are the only real hope for stopping these companies in their tracks (11). The Curaleaf warning letter includes examples of unsupported and unapproved claims made by the company that CBD companies should not be making and language that should raise a red flag, such as the following:

• "CBD has been demonstrated to have properties that counteract the growth of [and/or] spread of cancer."

• "CBD was effective in killing human breast cancer cells."

• "CBD has also been shown to be effective in treating Parkinson's disease."

• "CBD has been linked to the effective treatment of Alzheimer's disease ..."

• "CBD is being adopted more and more as a natural alternative to pharmaceutical-grade treatments for depression and anxiety."

• "CBD can also be used in conjunction with opioid medications, and a number of studies have demonstrated that CBD can in fact reduce the severity of opioid-related withdrawal and lessen the buildup of tolerance."

• "CBD oil is becoming a popular, all-natural source of relief used to address the symptoms of many common conditions, such as chronic pain, anxiety... ADHD."

• "What are the benefits of CBD oil? ... Some of the most researched and well-supported hemp oil uses include ... Anxiety, depression, post-traumatic stress disorders, and even schizophrenia .... Chronic pain from fibromyalgia, slipped spinal discs ... Eating disorders and addiction ..."

• "[V]ets will prescribe puppy Xanax to pet owners which can help in certain instances but is not necessarily a desirable medication to give your dog continually. Whereas CBD oil is natural and offers similar results without the use of chemicals."

• "For dogs experiencing pain, spasms, anxiety, nausea or inflammation often associated with cancer treatments, CBD (aka cannabidiol) may be a source of much-needed relief."

NASC has created a list of key questions veterinarians should ask when selecting CBD products or any animal health or nutritional supplement they are considering for their practice. Product labels only tell part of the story, and veterinarians must scrutinize a company's marketing materials — including their website — to truly understand what is being offered.

The following are some worthwhile questions to ask.

• Who formulates the product?

It is important to select products formulated by qualified professionals with specific knowledge and expertise

in formulating supplements for pets. Although there are great start-up companies offering innovative products, a company that has a solid track record of formulating and producing animal health products will have credibility and expertise a newer company may be lacking.

• What quality standards does the company follow?
Any company producing animal health and nutritional supplements should be able to identify the quality standards they follow. It is not enough for them to claim they follow current Good Manufacturing Practices (cGMPs). Their cGMPs should be modeled after FDA's cGMPs for human dietary supplements as defined in 21 CFR Part 111 and for animal food defined in 21 CFR Part 507 of the FD&C Act (12, 13).

• Are the company's products independently tested by an accredited third-party analytical laboratory?
The company should have someone on staff who can confirm they have a testing program in place for raw materials and finished products. Independent testing means they contract with a third-party analytical laboratory that verifies products purchased from the marketplace, just as consumers would, to ensure the products meet label claims and there are no contamination issues.

For hemp and CBD products, NASC members are required to verify testing of both raw materials and finished products, documenting the following: (1) THC is verified below 0.3%; (2) CBD content is verified to meet label claims; and (3) testing has been done for microbials, heavy metals, and pesticides.

• Is the product labeled properly?
Product claims: If a product label overtly claims — or even implies — that the product will treat, prevent, mitigate, or cure any disease, the supplier is breaking the law and misleading consumers. Outrageous product claims or *any* mention of a disease should be an immediate red flag.

Lot number: Although lot numbers do not guarantee quality, they do demonstrate that the manufacturer likely complies with some type of quality standards requiring product traceability. Lot numbers are essential in helping manufacturers notify customers in the event of a product issue.

• Does the product have the NASC Quality Seal?
The NASC Quality Program provides strict guidelines for product quality assurance in production (cGMPs), adverse event reporting, and labeling/claims standards. To display the Quality Seal on their products, a supplier must pass a comprehensive facility audit every 2 years, maintain ongoing compliance with rigorous quality requirements, and pass random independent product testing to ensure they meet label claims. The company must also sign a written code of conduct and participate in annual continuing education for quality, regulatory, and scientific advancement.

Cannabis and cannabis derivatives is a very dynamic, rapidly evolving, and also very potentially rewarding segment of the industry for both animal and human products. NASC will remain on the forefront of working to establish a responsible path forward for these types of products intended for dogs, cats, and horses. Veterinarians can best serve their clients by staying as current as possible, always keeping in mind that what is true today may change next week.

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Appendix

Comments for FDA Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments

Submitted by the National Animal Supplement Council by E-mail and Delivered at Public Meeting, May 31, 2019

Meeting Location:
USFDA White Oak Campus
10903 New Hampshire Avenue
Bldg. 31 Conference Center, The Great Room (Room 1503)
Silver Spring, MD 20993
Public docket FDA-2019-N-1482
On behalf of the members of the NASC, we appreciate the opportunity to share our experiences and challenges with cannabis-containing and cannabis-derived products, including information and views related to product risk to animals. We fully support and encourage the FDA to work with all states to ensure uniformity of policy and requirements for these products. We believe that will help provide consumers with consistent, high-quality, responsible options for their animals.

The NASC is the world's leading trade association representing companies marketing supplement products for dogs, cats, and horses. Our global membership includes raw material suppliers, contract manufacturers, and marketers of finished product brands provided in all channels of commerce. Our organization represents more than 90% of a $2.6 billion industry in the United States alone.

One of the primary differences is that in the animal industry, we are regulated at 2 levels: first, at the federal level by the CVM, and second, at the state level, typically by the state departments of agriculture or other state agencies with regulatory oversight, such as the office of the state chemist.

NASC was formed in 2001 with the objective of working cooperatively and transparently with the federal and state regulatory agencies and organizations such as the AAFCO to develop, define, and implement policies and practices that are in the best interests of all stakeholders, not least importantly, the animals themselves.

The animal industry is a fast follow industry in that whatever trends are most popular in the human industry will typically be in demand in the animal industry, especially with companion animals as the humanization of pets continues. This is the case with cannabis or cannabis-derived compounds. In fact, the popularity and demand for these products has progressed more rapidly than any trend I have seen in my 20 years in the business.

In our brief opportunity to comment, we would like to make the following primary points.
First, the regulatory agencies as well as the industry

Appendix *continued*

need a clearly defined, viable pathway for the marketing of these products on both the human and animal sides. We believe the FDA needs to provide clear guidance and definitions delineating compounds that would be considered approved drugs as opposed to those compounds extracted or derived from the whole plant and/or leaves and flowers from the *Cannabis sativa* L. plant. The resulting ingredient would contain a broad blend of constituents, including CBD, terpenes, trace THC, and other cannabinoids. We would ask the agency to move rapidly to clearly define the meaning of CBD concentrates and isolates. We fully support THC levels being limited to less than 0.3% for hemp.

Second, do these products pose undue risk to animals? We strongly believe that systems of continued vigilance and risk management are important. Full safety studies for every possible product combination are not economically feasible and consistent with the agency's risk-based approach. NASC has invested significantly in what we believe is the most advanced system of vigilance in the world for these types or products. The CVM, state agencies, and international regulatory bodies have access to data from our system. We provide visibility to regulators for companies marketing products as well as electronic product labels and adverse events, both serious and non-serious, which are trended and evaluated continuously.

Specifically, for hemp and hemp-derived compounds, we have the following data from the NASC database: (1) There are 149 products currently on the market; (2) some have been on the market for 10 years; (3) we have statistical analysis in mg/kg body weight for dogs, cats, and horses; and (4) there have been 9 adverse events reported, none of which were serious, in more than 18 million administrations in the 3 species mentioned above.

Although we agree that more research in all areas is needed, we very strongly believe that the data at this time suggest these compounds, provided by responsible companies, do not pose undue risk to dogs, cats, and horses.

Finally, due to the rapidly increasing demand for these products by consumers and with the considerable economic impact, we need a solution within a reasonable time frame. Given the rapidly increasing consumer demand, 2 to 3 years is simply not acceptable or realistic.

To that end, NASC has initiated the formation of a task force of industry experts to help define and present to the CVM a comprehensive pathway we believe is both viable and responsible for all stakeholders. We will be reaching out to the CVM for further discussions with action plans, milestones, and time frames.

As we proceed, we are in full agreement with the agency's position of taking action against irresponsible companies with obvious violations for egregious claims and irresponsibly marketed products. Although we have an excellent working relationship with the agency, we are disappointed that more action has not been taken against such irresponsible companies.

In closing, I would add that the majority of both the human and animal industries are responsible companies, and we also have a duty to educate our downstream business partners about irresponsible and opportunistic participants in our industry.

Thank you again for the opportunity to provide comments.