Regulatory Update 2021 Part 1: What We Are Watching In The Pet Products Sector

Pet Products:
As in the past, in the absence of any specific proposed legislation or regulatory proposals, we are monitoring discussions and research which may lead to pet food labeling changes and regulatory requirements for the sale of products containing CBD.

Pet Food:
We are monitoring discussions within the American Association of Feed Control Officials (AAFCO) – who works with the Food and Drug Administration ("FDA") to regulate pet food in the States – regarding a restructuring of labeling requirements. Some of the issues being discussed are:

- Pet Food Labeling Modernization efforts, which include a pet nutrition facts box similar to that used on human food and safe handling instructions;
- Implementation of a Human Grade process verification program;
- Work on Black Soldier Fly Larvae, Hemp, and other AAFCO ingredient definitions;
- Establishment of a Common Food Index;
- Issues relating to the declaration of vitamins and flavors on labels; and
- Concerns regarding vitamin K and copper sources in pet food

These proposed changes undergo a lengthy consideration process, and if approved are not expected to be implemented for a number of years. In an APPA webinar broadcast on June 15, Dr. Dave Dzanis, DVM, PhD, DACVN, provided an update on United States pet food regulatory developments over the past year. To access Dr. Dzanis's presentation, click here: https://appa.freestonelms.com/viewer/5WynZH3sGRwVrXjdtZmPpKRYfriht9iJYT81JspGryUoDzDfAQADty4h4ft7Dag1pp

States have also passed or are considering legislation affecting pet food producers. A bill is progressing in Minnesota (Senate Bill 1610 and companion House Bill 2014) that would allow cottage food producers (individuals who prepare and sell home-processed pet treats for dogs and cats) to sell homemade pet foods direct to consumers, provided certain conditions such as individual registration, non-hazardous ingredients, baked or dehydrate, labelling, etc.

Some states are considering modifying registration fees on pet food products or animal feed. Delaware Senate Bill 185 proposes raising the registration fee on manufactured cat and dog food over 3 years to $100 (from $23) per each product per brand. Oregon Senate Bill 36 amends the fee cap for registration of commercial feed brand, registration of commercial feed brand, and for animal feed manufacturing plant licenses.

CBD:

FDA Action

As consumer demand for CBD (cannabidiol) pet products continues to increase, so too does the development and marketing of these products. The United States Food and Drug Administration (FDA) has not expanded its approval of any CBD product beyond the one prescription human epilepsy drug (Epidiolex), and articulated its position on CBD in a notice posted on December 22:

The FDA's first priority is to protect the health and safety of Americans. Many questions remain regarding the science, safety, effectiveness and quality of products containing CBD," said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. "We remain focused on exploring potential pathways for CBD products to be lawfully marketed while also educating the public about these outstanding questions of CBD's safety. Meanwhile, we will continue to monitor and take action, as needed, against companies that unlawfully market their products — prioritizing those that pose the greatest risk of harm to the public.

In the December 22 notice, the FDA also announced that it issued five warning letters to companies for selling CBD products in ways that violated the Federal Food, Drug, and Cosmetic Act (FD&C Act). All five warning letters were directed at the illegal marketing of unapproved CBD products claiming to treat medical conditions, and included CBD products "that are especially concerning from a public health perspective due to the route of administration, including nasal, ophthalmic and inhalation." The letters also addressed violations relating to CBD added to food, and the impermissible marketing of CBD products as dietary supplements. Two letters were directed at CBD products illegally marketed for pets, including a product for use in the eye. https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products (FDA)

In a notice posted on January 8, 2021 and entitled Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products, the FDA acknowledged both the "rapid increase in the interest and availability of cannabidiol (CBD) products and other products derived from cannabis," along with its "limited understanding of the safety profile of CBD and many other cannabis-derived compounds, including potential safety risks for people and animals."

https://www.fda.gov/news-events/fda-voices/better-data-better-understanding-use-and-safety-profile-cannabidiol-cbd-products (FDA). According to the agency:

The FDA evaluates CBD just like any other substance we regulate, under a regulatory framework defined by law and with rigorous scientific evidence as a basis for both our regulatory approach and information we communicate.

We've consistently communicated concerns and questions regarding the science, safety, and quality of many of these products based on currently available evidence. We still don't have clear answers to important questions such as what adverse reactions may be associated with CBD products and what risks are associated with the long-term use of CBD products. Better data in these areas are needed for the FDA and other public health agencies to make informed, science-based decisions that impact public health.

The FDA described its approach to develop better information on CBD and on the CBD market as multi-pronged: engagement with stakeholders, including on the development of data on CBD use and safety; and, sampling and testing by the FDA of CBD products in the market. Moreover, the agency noted the importance of engaging with stakeholders to advance its ongoing efforts to systematically collect data on the safety and use of CBD. "At the same time, we see a critical opportunity for the FDA to work collaboratively with partners in government, industry, and academia to develop the foundation for more robust CBD data collection and analysis projects."

On January 21, the FDA further elaborated its position on CBD therapies and products, again acknowledging the "potential opportunities" offered by CBD products as well as "the significant interest" in such opportunities. Regardless, the FDA's notice was not without warning:
However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.
Also included in the notice were the FDA's online CBD product resources for both stakeholders and consumers. https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (FDA)

Legislative Action
On May 19, 2021, Senators Rand Paul (R-KY), Ron Wyden (D-OR), and Jeff Merkley (D-OR) introduced The Hemp Access and Consumer Safety Act of 2021, Senate Bill 1698 (the "Act"), which would establish a legal pathway for certain hemp-derived CBD products.
All CBD and CBD products currently are regulated by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (the "FDCA"). As the FDA has approved a CBD derivative for use in a currently marketed drug, under the FDCA CBD cannot lawfully enter the market as a food or dietary supplement at this time.
While the FDA has the authority to exempt items from this prohibition, it has yet to exempt hemp-derived CBD and therefore be able to regulate hemp-derived CBD like all other new dietary ingredients, foods, and beverages. The Act would "give hemp-derived CBD products an opportunity to lawfully be used in dietary supplements, foods and beverages under the Federal Food, Drug and Cosmetic Act," while at the same time, according to its' authors, "Prioritize consumer safety, requiring manufacturers to comply with all existing federal regulations for the products that contain CBD."
The bill was referred to the Committee on Health, Education, Labor, and Pensions. To access the bill, click here: https://www.congress.gov/bill/117th-congress/senate-bill/1698/all-info

On the state level, pending legislation in California, if passed, would amend its current laws to regulate industrial hemp products to include pet food. Current law prohibits the manufacture, sale, or delivery of a pet food ingredient or processed pet food that is “adulterated.” Assembly Bill 45 and Senate Bill 235 would provide that a dietary supplement, food, beverage, cosmetic, or pet food IS NOT adulterated by the inclusion of industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp if those substances meet specified requirements, and would prohibit restrictions on the sale of products such as pet food that include industrial hemp or cannabinoids substances.