

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, 31 May 2019

Meeting Location:

U.S. Food and Drug Administration
White Oak Campus
10903 New Hampshire Ave
Bldg. 31 Conference Center, The Great Room (Rm 1503)
Silver Spring, MD 20993
United States

Public docket [FDA-2019-N-1482](#)

On behalf of the members of the National Animal Supplement Council 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 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 National Animal Supplement Council 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 over 90% of a 2.6-billion-dollar industry in the United States alone.

One of the primary differences is in the animal industry as we are regulated at 2 levels;

First, at the Federal level by the Food and Drug Administration, Center for Veterinary Medicine, and second at the state level, typically by the state departments of agriculture or other state agency 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 like the Association of American Feed Control Officials 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 needs a clearly defined viable pathway for the marketing of these products on both the human and animal side.

- a. We believe 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.
- b. We would ask the agency to move rapidly to clearly define the meaning of CBD concentrates and isolates
- c. And, 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 of products. FDA, Center for Veterinary Medicine, state agencies, as well as international regulatory bodies, have access to data from our system. We provide visibility to regulators for companies marketing products, provide 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:

- There are 149 products currently on the market
- Some have been on the market for 10 years
- We have statistical analysis in mg. per kg. Body Weight for Dogs, Cats and Horses
- There have been 9 adverse events reported, none serious, in over 18 million administrations in the 3 species mentioned above

While we agree that more research in all areas is needed, we very strongly believe that the data at this time suggests these compounds, provided by responsible companies, does 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. 2-3 years is simply not acceptable nor realistic given the rapidly increasing consumer demand.

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

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. While 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.