U.S. Hemp Roundtable

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Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
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RE: FDA's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments. 84 Fed. Reg. 12969 - 12975 (April 3, 2019). Docket No. FDA-2019-N-1482.

The U.S. Hemp Roundtable ("the Roundtable") appreciates the opportunity to provide comments to FDA in response to its request for scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. The Roundtable is the hemp industry's leading business advocacy organization, committed to fostering regulatory discussions about hemp products and building an accountable industry. With members from more than seventy firms from across the country, the Roundtable's Board of Directors and members constitute many of the hemp industry's largest businesses. We are also closely aligned with the Hemp Industries Association ("HIA"), the industry's leading trade association and grassroots force. Together with HIA, the Roundtable has worked toward fostering increased accountability for the hemp-derived consumer product industry by providing high standards, best practices and self-regulation, giving confidence to consumers and law enforcement that hemp products are safe and legal.

Although FDA's request for comments broadly references "cannabis" and "cannabis-derived compounds" our comments are limited to hemp extracts and constituents such as cannabidiol ("CBD"), which may be used as ingredients in products intended for use in humans and animals, including supplements, foods, and cosmetic products. The Roundtable supports FDA's efforts to ensure that products containing hemp and CBD are manufactured in a safe, consistent manner and accurately labeled. We also appreciate FDA's willingness to work with stakeholders to develop an appropriate framework for hemp-derived CBD as a dietary supplement and food ingredient. We believe Congress clearly intended to have CBD and hemp products

available to consumers in a wide range of product categories – including food and dietary supplements – when it passed the Agriculture Improvement Act of 2018.[1]

We also believe that FDA has all the tools necessary to expeditiously issue a rule allowing CBD in foods and dietary supplements. The Federal Food, Drug, and Cosmetic Act ("FD&C Act"), along with FDA's robust implementing regulations, provide the necessary framework to ensure that hemp-derived products are appropriately manufactured, labeled, and marketed, and safe for consumers. This framework provides the flexibility necessary to accommodate the different formulations of hemp-derived ingredients on the market while also allowing for continued innovation and scientific advances. However, we believe FDA must act swiftly as a growing number of hemp-derived CBD products on the market, whether labeled as dietary supplements, food or cosmetics, can put consumers at risk due to poor quality or misleading claims.

We also recognize FDA's concerns regarding issuance of a regulation that would make an exception to Section 201(ff)(3)(B) of the FD&C Act and allow the use of hemp-derived CBD as a food and dietary supplement. As explained in our comments, many of the answers to FDA's questions regarding the safety and potential risk to consumers will depend on the specific composition of the hemp-derived ingredient, product formulation, and intended use of the product at issue. For foods and dietary supplements, the Generally Recognized as Safe ("GRAS") and the new dietary ingredient ("NDI") notification process provide the mechanisms to establish the safe use of these products. Based on the safety information in the published scientific literature and the data compiled by Roundtable members and the HIA, hemp-derived ingredients at the dosages commonly used in food, dietary supplements, and cosmetics do not appear to pose safety risks to consumers and therefore can be regulated by FDA like any other botanical ingredient used in these products. In addition, we firmly believe that action by FDA to expressly permit the use of CBD-containing hemp ingredients in food and dietary supplements will not serve as a disincentive to drug development, as there are several examples of ingredients that have successfully co-existed as drugs and dietary supplements/food, such as fish oil and niacin.

While we believe FDA's existing regulatory framework for these product categories provides the necessary guardrails for the safe production and marketing of products, we recognize that hemp-derived ingredients such as CBD have unique considerations. Therefore in our comments we also offer additional industry resources the agency can utilize to help assure quality and safety of hemp and CBD products. Together with FDA's existing rules and regulations, we believe the agency has sufficient means to address the safety, quality, and appropriate labeling of food, dietary supplements, and cosmetics that contain hemp-derived ingredients.

A. Health and Safety Risks

[1] Press Release from Senator Mitch McConnell, *Leader McConnell Discusses Hemp, CBD with Acting FDA Commissioner*, June 27, 2019, *available at* https://www.mcconnell.senate.gov/public/index.cfm/pressreleases?ID=0B71B14E-5F77-4283-9084-561F67EFBC70.

1. **Safety of CBD and Hemp-Derived Ingredients**

The available scientific evidence demonstrates that CBD is generally well tolerated, even at high doses, in healthy and non-healthy populations (Iffland, 2017). Last year, the World Health Organization ("WHO") concluded there are no public-health related concerns associated with the use of CBD nor is there any evidence of CBD recreational use. As described in the report, WHO recognized that CBD does not produce the highs that are seen with delta-9 tetrahydrocannabinol ("THC"), and in experimental models of abuse liability, CBD exhibited no effects indicative of any abuse or dependence potential (WHO Report, 2018).

Furthermore, FDA's own scheduling recommendation on CBD concludes that based on clinical and available epidemiological data, "there is little indication that CBD has abuse potential or presents a significant risk to the public health."[2] In 2016, Food Standards Australia New Zealand also evaluated the safety of CBD and determined that CBD is well tolerated at doses greater than 1000 mg per day and that there were no reports of adverse effects of oral CBD in the literature (Cannabidiol Hazard Assessment, 2016).

CBD has been evaluated in healthy adults using a variety of tests for abuse potential as well as physiological effects. In general, clinical studies have reported that even high doses of oral CBD does not produce the same effects that are characteristic of THC (Grotenherman, 2016 and Consoroe, 1979). For example, a single dose administration of CBD at 600 mg did not differ from the placebo on scales of the Addiction Research Centre Inventory ("ARCI"), a 16 item Visual Analog Mood Scale, and subjective measurements of intoxication or psychotic symptoms (Martin-Santos, 2012). In contrast, 10 mg of oral THC administration was associated with subjective intoxication and euphoria as well as increased psychotic symptoms and changes in ARCI scales reflecting sedation and hallucinogenic activity. In another recent study of CBD in healthy adults, consisting of three arms, CBD was administered in single ascending dose (1500, 3000, 4500, or 6000 mg CBD), multiple dose (750 or 1500 mg twice daily) and food effect (1500 mg CBD single dose) (Taylor, 2018). The results indicate that CBD was well tolerated with most adverse events being of mild severity with no severe or serious events. The most common adverse events were diarrhea, nausea, headache, and somnolence across all trial arms.

Even in highly sensitive populations of recreational polydrug users, CBD is associated with minimal abuse potential. In one study, highly purified CBD was administered in single dose (750 mg, 1500 mg, and 4500 mg) and compared to that of single oral doses of alprazolam (2 mg), dronabinol (10 mg and 30 mg), and placebo in healthy recreational polydrug users (Schoedel, 2018). The primary endpoint was the maximum effect (E_{max}) on Drug-Liking visual analog scale (VAS). Compared with placebo, Drug-Liking was not significantly different for subjects taking 750 mg CBD. Drug-liking E_{max} values for 1500 mg and 4500 mg CBD were significantly different from the placebo, but the mean differences were less than 10 points on the

[2] Letter from Brett P. Giroir, Assistant Secretary of Health to The Honorable Robert W. Patterson, Acting Administrator, Drug Enforcement Administration (My 16, 2018), *available* at https://hempindustrydaily.com/wp-content/uploads/2018/10/DHS-DEA-letter-2018-0014-0002.pdf.

VAS scale compared to greater than 18 point differences between positive controls and the placebo. Furthermore, in contrast to alprazolam, CBD administration had no observable effect on cognitive/psychomotor tests and the majority of adverse events were of mild to moderate severity with no serious adverse events reported. The most common adverse events included somnolence, diarrhea, headache, and abdominal pain.

Most CBD studies in humans involve acute CBD dosing in healthy and non-healthy subjects, in part because the research has been limited due to CBD and hemp being misclassified as Scheduled I controlled substances. However, studies in chronic dosing of CBD also demonstrate that CBD is well tolerated when taken for an extended period of time. In the largest study thus far, 261 patients with epilepsy received CBD together with their regular medication. Ten percent of the patients reported side effects of tiredness, diarrhea, and exhaustion (Iffland, 2017). In another review article on the administration of CBD in epileptic patients, the journal evaluated 35 papers that all studied CBD with a placebo comparator. The dosing ranged from 2.5-20 mg/kg/day across a mean treatment length of 14 weeks. Furthermore, earlier studies reviewed also reported using a dosage of 100 mg of CBD administered 2-3 times per day for a treatment period between 8 and 26 weeks. The review concluded that administration of CBD reduced seizure frequency, improved aspects of quality of life, and was generally well tolerated with mild-to-moderate adverse events. Notably, most of the larger randomized controlled trials that were reviewed were in children and adolescents (Stockings, 2018).

In June 2018, FDA determined that CBD was safe and effective for the treatment of specific forms of epilepsy at doses of 5 mg/kg twice daily (CDER, 2018). In its review, the Agency noted the most commonly observed adverse events included somnolence and sedation, gastrointestinal, hepatic, and infection, which were generally mild to moderate in severity. Serious adverse events were related to transaminase elevations, somnolence and lethargy, and infections. Although FDA noted the potential for serious liver injury, the Agency also concluded that such risk "can be appropriately managed with inclusion of relevant language in labeling."

Based on the available data, we believe that there are no unique safety concerns associated with the consumption of CBD that would preclude the use of FDA's current regulatory framework in establishing product-specific acceptable levels of use. We expect there to be more and continued research of various uses of CBD following the creation of a clear legal pathway for these products. As discussed in our summary, we believe the pathway for these products should take into account the intended use of the product, which will dictate the acceptable safety levels permissible for hemp-derived CBD and other hemp extracts in food, dietary supplements, and cosmetics.

While pure CBD studies have demonstrated that CBD is well tolerated even at doses as high as 6000 mg, hemp extracts with other cannabinoids may act differently based on the formulations. Therefore, each formulation should undergo its own safety review under the current regulatory framework that FDA uses to assess the safety of food and dietary ingredients. We anticipate the levels of use in food and dietary supplements will be distinguishable from those approved for use in diseased populations such as patients with severe epilepsy. However, we do not recommend setting a strict limiting standard on the amount of hemp extract or CBD as the effects of these ingredients will likely be impacted by the specific product formulation.

a. Additional Product Safety Data for Humans and Animals

Both the Roundtable and HIA surveyed members for additional product safety data that may be useful to FDA in its assessment of CBD. Three of our member companies have provided detailed reports of adverse events received over one- to two-year periods. (Attachment 1 – Adverse Event Report Data). Not only does this data show that adverse events overall (both serious and non-serious) are very low for hemp extracts and CBD products, it also demonstrates that companies are complying with the post-market surveillance requirements mandated by the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006.

As shown in the attached materials, one of our member companies sold approximately 580,000 products with zero serious adverse events reported to the company, and about 300 non-serious adverse reported for humans and animals. Another member company has sold over 1.4 million products, with zero serious adverse events and 623 non-serious adverse events. This company has also provided a thorough breakdown of its reported adverse events in the attached materials. A third member company provided a summary of adverse events/complaints related to human ingestion or topical application of their products along with the percentage of adverse events/complaints per units sold. A fourth company provided adverse events related to human ingestion and topical products reporting approximately 200 adverse events and zero serious adverse events, with over 2 million products sold. Notably, the percentage of AERs for these companies (serious and non-serious) is 0.01-0.1 percent.

There are also various institutions that are developing systems to collect safety information about products containing cannabis and cannabis-derived compounds. For example, as mentioned at FDA's May 31st hearing, ValidCare, LLC, a Colorado company, is developing a self-reporting, self-monitoring system that seeks to gather data from CBD and hemp product users, including the side effects of the products they are consuming. The system specifically includes the reporting of adverse events and will be marketed directly to the general public. ValidCare has also submitted comments to FDA regarding this system.

With regard to data in animals, the National Animal Supplement Council has submitted comments to FDA that included the following information from the NASC database regarding hemp and hemp-derived compounds:

- "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"

NASC notes that while it agrees additional research is needed, "the data at this time suggests these compounds, provided by responsible companies, does not pose risk to dogs, cats and horses." (Attachment 2 – NASC Comments to FDA.)

2. **Mode of Delivery**

The Roundtable is primarily interested in promoting the marketing of CBD and hemp-derived ingredients in dietary supplements, food, and cosmetics via oral and topical routes of administration. Cannabis is widely consumed in human populations by different modes of delivery, and each mode produces unique and different effects on human physiology, in large part because the pharmacology of cannabis-derived compounds varies depending on the route of consumption. Historically, patients and recreational drug users have inhaled or vaporized cannabis compounds for quick onset and higher peak concentrations (Campbell, 2017). However, as discussed above, CBD does not produce the same highs as other cannabis compounds like THC, nor does it have the same abuse potential. Therefore, we do not expect vaporization to be a common route of administration for CBD and other hemp-derived ingredients.

Clinical investigations indicate that the oral bioavailability of CBD is low (13-19%) because it undergoes extensive first pass metabolism and its metabolites are mostly excreted via the kidneys (Millar, 2018). In a review of pharmacokinetic studies in humans, the reported half-life of CBD was between 2-5 days after chronic oral administration, 1.09-1.97 hours following single oral administration (10 and 20 mg), and 2.95-3.21 hours following administration of 10 mg oral lipid capsules (Millar, 2018). Therefore, even amongst the same mode of delivery, the effects and half-life of CBD is very different depending on the dosing and formulation. Amongst other routes of administration the half-life of CBD also varied between 1.1 and 2.4 hours following nebulizer and aerosol administration (20 mg), 1.44-10.86 hours after oromucosal spray administration (5-20 mg), 24 hours after intravenous infusion, and 31 hours after smoking. Only one study reported the bioavailability of CBD in humans, which was 31% following smoking. Furthermore, in comparison to oral/oromucosal routes, the area under the curve and C_{max} increase in dose-dependent manners are reached quicker following smoking/inhalation. C_{max} is also increased during fed states and in lipid formulations.

Another study evaluating the bioavailability of CBD following nasal and transdermal applications suggests that oral administration of CBD is not ideal for therapeutic delivery because the oral bioavailability is so low (between 6% to 33%) (Paudel, 2010). Therefore the study examined the intranasal and transdermal delivery potential of CBD. Intranasal applications of CBD resulted in relatively rapid and significant absorption of CBD from the nasal cavity (10 minutes) with a bioavailability of 34-46%. The bioavailability did not improve with permeation enhancers. Through transdermal administration CBD provided significant plasma drug levels (6.3 ± 2.1 ng/mL, which was attained at 15.5 ± 11.7 hours) after topical gel application in vivo. Transcutol HP enhanced the CBD steady-state plasma concentration by 3.7-fold.

3. **Drug Interactions**

As discussed, CBD is generally well tolerated in healthy adults where even at high doses only mild adverse events have been reported in several scientific studies. However, because CBD is extensively metabolized in the liver, and *in vitro* data suggests that it may inhibit the CYP2C family of isozyme and CYP3A4, as well as UBT1A9 and UGT2B7, it is important to understand if any of these signals translate to impacts on drug-drug interactions *in vivo* (Taylor, 2018). For example, CBD is metabolized mainly by the

cytochrome P450 (CYP) 2C19 and CYP3A4 isoenzymes, which are induced by some antiepileptic drugs ("AEDs") and inhibited by others.

There have been reports of potential *in vivo* drug-drug interactions with some commonly prescribed epilepsy drugs. For example, one study in children diagnosed with Dravet syndrome found that multiple dosing of CBD in patients on regimens containing clobazam resulted in an increase in its major active metabolite N-desmethylclobazam (Devinsky, 2018). However, there were no other interactions with several AEDs, and all 3 doses of CBD (5, 10, and 20 mg/kg/day) were generally well tolerated. However, the CBD group did result in more adverse events than the placebo. Other studies have found similar results in both children and adults taking AEDs along with CBD, which resulted in elevated liver function with sedation being the most common side effect (Gaston, 2017 and Geffrey, 2015).

More research on drug-drug interactions should be conducted to understand the extent of CBD administration with other forms of medication. However, even in the above referenced studies, CBD was well tolerated in individuals that were ill and taking other medications to treat epilepsy. Thus, we believe concerns regarding potential drug-interactions can be mitigated through consumer communication and education.

4. **Vulnerable Populations**

As with any other ingredient intended for use in foods, dietary supplements, or cosmetics, vulnerable human populations must be considered when assessing the safety of the products. While CBD has been well tolerated, even in studies with children with Dravet syndrome and refractory epilepsy, the research on CBD in vulnerable populations is still emerging (Devinsky, 2018 and Geffrey, 2015). Similar to any other dietary supplement or food ingredient, there are ethical considerations to conducting studies in healthy vulnerable populations such as children and pregnant and lactating women. However, as discussed above, there are no unique safety concerns associated with CBD compared to other dietary or food ingredients.

In a recent observational label study of 188 children and adolescents with autism spectrum disorder (mean age 12.9 ± 7 years), patients were treated with an oil containing 30% CBD and 1.5% THC, on average 79.5 ± 61.5 mg CBD and 4.0 ± 3.0 mg THC, three times a day. The most common side effects, reported at six months by 23 patients (25.2%, with at least one side effect) were: restlessness (6 patients, 6.6%), sleepiness (3, 3.2%), psychoactive effect (3, 3.2%), increased appetite (3, 3.2%), digestion problems (3, 3.2%), dry mouth (2, 2.2%) and lack of appetite (2, 2.2%). The study concluded that the "treatment appears to be safe and side effects reported by the patients and parents were moderate and relatively easy to cope with." (Bar-Lev Schleider, 2019).

In a small observational study of 12 females (mean age 16.7 years) investigating the use of CBD-enriched hemp oil to relieve symptoms and improve the quality of life in young with adverse drug effects following human papillomavirus vaccine, patients were treated with 25 mg/ml per day divided into twice-daily dosages, then supplemented by 2–5 mg/ml CBD once a week until intolerance or a maximum dose of 150 mg/ml CBD per day was reached over a three-month period. Only two of 12 patients (16%) withdrew from the

study due to an adverse event (hyperglycemia in one patient with diabetes mellitus, moderate sleepiness and confusion in the second patient) and no significant adverse effects were observed in the patients throughout the trial (Palmieri, 2017).

In general, there has been limited research on the effects of chronic exposure to low doses of hemp extracts or CBD. Therefore, as with any other supplement, caution should be taken before allowing vulnerable populations to consume supplements containing hemp-derived ingredients. We believe concerns regarding vulnerable populations can be addressed by labeling and post-market adverse event monitoring. Many dietary supplements on the market include advisories or special labeling instructions for specific populations such as children or pregnant women. Similarly, any potential safety concerns with CBD in vulnerable populations could be addressed by labeling.

5. **Safety Monitoring for Adverse Events**

We recognize that continued safety monitoring is necessary to ensure long-term use and exposure to these products continues to present no safety concerns. We recognize that innovative research on the various forms of CBD and hemp-extracts has been stalled in part due to the Scheduled I Controlled Substance status of these products until recently, which has prevented innovations in research especially in healthy populations at levels below those typically used in drug clinical trials. However, as discussed above, in the research that has been conducted, there have been no signals of a clinically meaningful safety concern for these products.

We believe FDA's mandatory adverse event reporting system for dietary supplements and voluntary reporting system for cosmetics and food will provide crucial post-market safety information once the Agency establishes a clear regulatory pathway for hemp-derived ingredients. As there are no unique safety concerns for CBD, we believe FDA's current post market surveillance systems are sufficient.

As discussed above, there are some concerns related to drug-drug integrations with therapeutic doses of CBD in patients taking other commonly prescribed epilepsy drugs. However, because the bioavailability of CBD is low across various modes of delivery (i.e., oral consumption, nasal, and transdermal), and CBD is well tolerated even at high doses, we do not believe there are specific safety concerns that would result from the overlap of low chronic exposure to CBD in the form of dietary supplements and therapeutic dose levels. However, any potential concerns could be mitigated through appropriate labeling advisories for consumers that are taking therapeutic forms of CBD, e.g., directing consumers to consult a physician before taking dietary supplements of food containing CBD or other hemp-derived ingredients.

6. **Margin of Exposure**

As discussed above, it is difficult to set maximal acceptable daily intake levels of hemp-derived products because the levels and modes of delivery in the general population vary greatly. Therefore, the margin of exposure of any product will be based on its intended use and formulation. For example, the exposure for pure CBD will likely be different from hemp extracts.

As with any dietary supplement, food, or cosmetic ingredient, FDA's current regulatory framework is sufficient to evaluate safety concerns of hemp-derived ingredients, including CBD. For example, FDA's GRAS procedures provide that firms must evaluate the substances dietary exposure. This includes an evaluation of any self-limiting levels of use and the history of consumption of the substance by a significant number of consumers. Similarly, NDI notifications often provide evidence that the substance was safely consumed as a food or dietary supplement. This may include information about the mean and high (e.g., 90th percentile) exposure levels and intake level of the dietary ingredient based on the intended conditions of use, or related scientific evidence on the ingredient. Furthermore, the safety assessment should describe and discuss situations in which conditions of use and composition of the new dietary ingredient differ from the documented conditions of use. Therefore, the burden of establishing margins of exposure for hemp-derived ingredients will be on the manufacturers completing the self-GRAS process, or submitting GRAS and NDI notifications to FDA.

7. **General Use in Food**

In December 2018, the FDA issued three "no questions letters" in response to GRAS notifications for hemp seed-derived food ingredients. Therefore, companies have already used FDA's regulatory framework to establish the safety of cannabis-derived products for use in food. In addition, cannabis has been grown in various locations around the world and has commonly been used in cooking as an herb, an additive, and also consumed as tea (Booth, 2004). In recipes, cannabis has been used in beverages and added to home-made sweets, biscuits, and cakes.

In 2018, Roundtable member CV Sciences published a study examining the genotoxicity and subchronic toxicity of hemp extract to understand its toxicological profile as part of its self-affirmed GRAS assessment. A battery of toxicological studies were conducted on the hemp extract containing about 25% cannabinoids. No evidence of genotoxicity was found and a 14-day repeated oral dose-range finding rat study at 1000, 2000, and 4000 mg/kg bw/day resulted in effects where a NOEL could not be concluded (Marx, 2018). Based on those results, a 90-day repeated dose oral toxicity study was performed in rats using doses of 100, 360, and 720 mg/kg bw/day, followed by a 28-day recovery period for two satellite groups. Significant decreases in body weight, body weight gain, and differences in various organ weights compared to controls were observed. At the end of the recovery period, many of the findings were trending toward normal; thus, the changes appeared to be reversible. The NOAEL for the hemp extract was determined to be 100 mg/kg bw/day for males and 360 mg/kg bw/day for females. The study concluded that the hemp-extract was nonmutagenic, nonclastogenic, and nongenotoxic in the current bacterial reverse mutation, in vitro mammalian chromosomal aberration, and in vivo mouse micronucleus tests, respectively.

Recently, Manitoba Harvest also announced that it completed a safety assessment and self-affirmed its Broad Spectrum Hemp Extract as GRAS. The GRAS applies to the intended use in products for the general population age 2 years and older excluding pregnant and lactating women. Its hemp extract products include 15 mg CBD plant protein powder, 10 mg CBD oil drops, 5 mg CBD oil spray, and 15 mg CBD oil soft gel formats (Manitoba, 2019).

8. **Impact of Commercial Availability of Non-Drug CBD Products on Incentives for Drug Development**

We believe the widespread commercial availability of CBD-containing food and dietary supplements will not have a significant effect on the incentives for drug development. The fact that an ingredient can be studied or used as a drug is not a fundamental consideration when determining how a product should be regulated by FDA. Rather, the intended use of a product – typically based on labeling claims – will determine how FDA will regulate the product under the FD&C Act. The law also sets clear boundaries that prohibit the promotion of a product to diagnose, cure, mitigate, treat, or prevent disease without approval from FDA, thereby preserving the ability of drug companies to research and market products for these uses. This system has allowed products such as fish oil and pre-natal vitamins to co-exist as both as drugs and dietary supplements for many years without negatively impacting drug development.

Like other ingredients used in FDA-regulated products, CBD and other hemp-derived ingredients continue to be studied for both serious medical conditions as well as mild conditions amenable to self-treatment. The FD&C Act provides the means to promote products for these uses in a manner that clearly distinguishes drugs from food, dietary supplements, and cosmetics – even in cases where there is overlap among ingredients used in these products. FDA has sent numerous Warning Letters to companies marketing products, including CBD products, for conditions that caused these products to be unapproved drugs. We encourage FDA to continue these efforts and to take further enforcement action, such as seizures or injunctions, in cases where companies willfully ignore the law.

Further, under these same laws, manufacturers are already required to determine what levels of CBD and hemp ingredients are acceptable for non-drug products based on the adulteration provisions specific to these products. Additional mechanisms such as the NDI provisions of the FD&C Act and GRAS procedures provide further means for establishing safe levels of these ingredients. Therefore, we do not believe that it is necessary for FDA to establish threshold levels for hemp-derived CBD as these levels will vary based on the composition and intended use of the product.

Summary of Recommendations:

- CBD does not appear to pose unreasonable safety risks to consumers and therefore can be regulated by FDA like any other botanical ingredient used in these products. This position is supported by clinical studies conducted at dosages at or above what is commonly used in dietary supplements, food, and cosmetics. Several of these studies are in sensitive populations.
- Appropriate levels of CBD will be much lower in food and dietary ingredients than those used in pharmaceutical products. However, we advise against establishing arbitrary dose limits for these products as the effects of the CBD will vary greatly based on the intended use, formulation, and mode of delivery. Each manufacturer has the burden to establish its specific product formulation is safe for the intended population through FDA's current regulatory framework.

- Safety concerns that may arise from the lack of data in vulnerable populations such as children, pregnant or lactating women, and patients taking therapeutic levels of CBD can be addressed in the labeling of the product with adequate advisory language and directions for use.
- FDA's current regulatory system supports incentives for drug development, and clearly and sufficiently distinguishes these products from food and dietary ingredients based on their intended use and labeling.

B. Manufacturing and Product Quality

1. Safety Standards Related to Manufacturing, Processing, and Holding Hemp-Derived Products

The FDA's existing current Good Manufacturing Practices ("cGMPs") for food and dietary supplements establish mandatory standards for sanitary operations, training, processes and controls to ensure that products and their ingredients are not contaminated with harmful or undesirable substances such as pesticides, biological hazards, heavy metals, or other impurities. Additional safety measures put in place by the Food Safety Modernization Act ("FSMA") requires a hazard analysis and risk-based preventive controls for all foods and dietary ingredients. Further, FDA's implementing rules related to FSMA impose food safety-related requirements for both food and dietary supplements. Thus, like any other botanical product, CBD and other hemp-derived products labeled as dietary supplements or food are subject to comprehensive and robust standards to ensure products are manufactured and held in a safe manner. In fact, it is imperative that the hemp food and supplement industries have FDA oversight to protect the public from products made without cGMP manufacturing standards. We encourage FDA to continue to use its authority under the FD&C Act to enforce against companies that fail to meet these standards as the products would be considered adulterated or misbranded under the law.

Although cosmetics are not subject to mandatory cGMPs, these products are also subject to adulterations provisions under the FD&C Act. Therefore cosmetics that contain hemp-derived CBD must be manufactured and processed in a manner that ensures the safety of the final product.

For hemp and CBD dietary supplements, we note that 21 CFR Part 111 requires dietary supplement firms to take a number of actions prior to using hemp-derived ingredients. We believe these requirements thoroughly address important sourcing, supply chain, and safety issues, such as:

- Establishing the identity of the ingredient using appropriate methods and testing that is specific to the ingredients, and maintaining documentation demonstrating that such testing is fit for purpose
- Using appropriate methods for extraction, concentration, and purification processes, which demonstrates knowledge of the ingredient manufacturing process
- Characterization of all components of the ingredient, including all cannabinoids and other plant compounds, as well as setting and meeting specifications for these components
- Use of scientifically valid test methods and acceptance criteria that are specific, accurate, and precise
- Use of stability studies and data to substantiate expiration dating

The Roundtable requires its members to follow all applicable federal requirements including those provided in the FD&C Act and encourages its members to adopt voluntary best practices where available, such as FDA's Draft Guidance for Industry on Cosmetic Good Manufacturing Practices[3] and AHPA's Guidance on Good Agricultural and Collection Practices and Good Manufacturing Practices for Botanical Materials.[4]

In addition, the U.S. Hemp Authority Certification Program Guidance (hereinafter "the Guidance") provides high standards, best practices and self-regulation throughout the supply chain to give consumers confidence that hemp products are both safe and legal.[5] This effort is funded by the Roundtable and joined by organizations such as HIA, and provides comprehensive guidance for growers and processors of hemp and was developed by the industry's leading firms, top-tier testing laboratories, and quality assessors. Hemp product producers that meet the stringent self-regulatory standards of the U.S. Hemp Authority and pass a third-party audit are eligible to use the Certified Seal of the U.S. Hemp Authority.

The Guidance includes standards for growers, processors/manufacturers, and brand owners that address the following key components of safety:

- Personnel guidance, including safety measures, sanitation procedures, and employee training
- Standards for physical plants and grounds
- Supplier qualification and specifications
- Contaminant Testing and Hemp Cannabinoid Quantification, which includes testing for and acceptable levels of contaminants (e.g., heavy metals, microorganisms, pesticides and residual solvents), based on guidance published in the American Herbal Pharmacopoiea (AHP) Cannabis monograph and the American Herbal Products Association (AHPA) Guidance Policies
- Cannabinoid potency methods to determine the concentration of cannabinoids and effectively distinguish cannabis as either legal hemp or marijuana
- Storage and distribution of hemp and hemp products
- Quality controls related to product complaints, adverse events, and recalls

2. **Standards and Processes to Ensure Manufacturing Quality and Consistency of Products**

In addition to meeting safety standards, hemp-derived products must be produced in a manner that assures the quality and consistency of the final product. The federal cGMPs for dietary supplements and food mandate that manufacturers have quality controls in place to ensure product integrity and that products have

[3] U.S. Food and Drug Admin., Draft Guidance for Industry: Cosmetic Good Manufacturing Practices (June 2013), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices.
[4] American Herbal Products Assoc., Guidance on Good Agricultural and Collection Practices and Good Manufacturing Practices for Botanical Materials (March 2017), *available at* http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Documents/AHPA_Good_Agricultural_Collection_Practices_Good_Manufacturing_Practices_Botanical_Materials.pdf.
[5] U.S. Hemp Authority™ Certification Program, Guidance Procedures Growers Processors / Manufacturers Brand Owners (May 27, 2019), *available at* https://www.ushempauthority.org/docs/US-Hemp-Authority_Certification-Program-Guidance_05-28-19.pdf.

been manufactured, packaged, labeled, and held under conditions to prevent adulteration. The cGMPs for dietary supplements also require that products meet established specifications for identity, purity, strength, and composition, and limits on contaminants.

Similar to other botanical substances, hemp ingredients have varying levels of constituents depending on factors such as where the starting hemp material was grown and the specific strain of hemp. Robust quality systems are essential for ensuring that hemp products that contain CBD and other active plant compounds are accurately labeled and meet all label claims.

In addition to the components listed above that address safety, the U.S. Hemp Authority Guidance also provides detailed standards for quality management systems ("QMS") for hemp products. These standards address, among other things, quality control procedures and guidance for packaging, labeling, and other related operations to ensure that hemp products are packaged and labeled as specified in the manufacturing record.

3. **Validated Analytical Testing to Support the Manufacturing of Safe and Consistent Products**

Validated analytical testing is necessary to help ensure that hemp-derived CBD food, supplements, and cosmetics meet the standards for safety and quality discussed above. The Roundtable supports the efforts of organizations such as the American Society for Testing and Materials ("ASTM") International, American National Standards Institute ("ANSI"), and the U.S. Pharmacopeial Convention ("USP") to develop reference test methods and consensus standards for the manufacturing and testing of cannabis-derived ingredients such as CBD to ensure the quality and safety of these products.

The U.S. Hemp Authority Guidance also advises that laboratories adopt methods developed by the Association of Analytical Communities ("AOAC") to help ensure that methods for measuring cannabinoids are fit for purpose, accurate, and provide precision especially with regard to quantifying THC concentrations in products.

In rulemaking and/or guidance, FDA should mandate the use of validated analytical test methods to support the manufacturing of safe and consistent products that meet labeling claims. Such testing methods would help ensure that the amount of cannabinoids, terpenes, and other compounds, depending on the specific product, are accurately labeled and that contaminants are detected.

4. **Standardized Definitions for Ingredients**

Currently there are no standardized definitions for the various types of hemp-derived ingredients used in dietary supplements, food, and cosmetics. We are aware that companies use terms such "full spectrum hemp extract" and "broad spectrum hemp extract" to describe the composition of certain hemp-derived ingredients, primarily for marketing purposes. For example, "full spectrum hemp extract" often refers to hemp extract that contain all constituents found in hemp (including trace amounts of THC). Broad spectrum hemp extract

typically refers to extracts that contain no detectable level of THC and an array of cannabinoids, terpenes and other constituents found in hemp, with the exception of THC.

Regardless of the specific terms used, we believe products should be accurately labeled and any terms used to describe a product or its ingredients should reflect the actual contents. Should FDA determine that standardized definitions are necessary, the Roundtable encourages the agency to work with industry stakeholders to develop appropriate definitions for CBD and other hemp-derived products.

5. **Functional Purposes of Hemp-Derived CBD in Food**

Manufacturers add hemp-derived ingredients such as CBD to foods, including dietary supplements, for the purpose of enhancing the food's nutritive value and providing health and wellness benefits. We believe consumer perceptions and expectations regarding foods that contain hemp-derived CBD are generally consistent with manufacturers' intent. Probiotics in yogurt and omega-3 fatty acids found in fish are consumed for similar reasons.

Summary of Recommendations:

- The Roundtable urges FDA to use its existing authority under the FD&C Act to enforce the mandatory cGMPs to protect consumers from unsafe products and ensure that all hemp-derived products are produced in a quality, consistent manner and accurately labeled.
- We also encourage FDA to consider adopting the standards provided in the U.S. Hemp Authority Guidance and work with standard-setting organizations such as ASTM, ANSI, AOAC, and USP to develop validated analytical testing and consensus-based standards for quality and safety. In future guidance or rulemaking, we also recommend that FDA to include consensus-based, validated standards and methods for cannabinoid content, specifically CBD and THC.
- If FDA determines that standardized definitions are necessary, we encourage FDA to work with industry stakeholders to develop these definitions.

C. Marketing, Labeling, and Sales of Hemp and CBD Products

1. Informing Consumers About Potential Risks Associated with Hemp and CBD Products

The adulteration and misbranding provisions of the FD&C Act apply to all products labeled as for dietary supplements, foods, and cosmetics; thus, products must be safe when used under the conditions prescribed in labeling, or under ordinary conditions of use. Further, under the misbranding provisions of the Act, product labeling cannot include false or misleading information. Depending on the specific composition, dosage, and intended use of the product, the directions for use and potential advisories will vary from product to product. Although the safety of CBD is well established, as discussed in Section A., minor side effects and drug interactions have been associated with CBD. Like other ingredients on the market, there is currently a lack of data on the effects of CBD and other hemp-derived ingredients on vulnerable populations such as children and pregnant women. Therefore certain consumers and subpopulations may benefit from label advisories on products that contain CBD or other hemp-derived ingredients.

In addition to mandating that all dietary supplements and food be labeled in accordance with FDA regulations, the U.S. Hemp Authority Guidance provides that all products containing measurable amounts of cannabinoids should include proper advisories and cautions, such as the following:

- This product should be used with caution when driving motor vehicles or operating heavy machinery.
- Use this product under the guidance of a physician if you have a medical condition, are pregnant or lactating.
- Keep out of the reach of children.
- This product meets federal requirements for hemp products, however consumption may be flagged by some drug tests.

2. **State Approaches to Regulating CBD-Containing Food Products**

States currently take a wide variety of approaches to regulating hemp-derived products including CBD. Several states have enacted legislation that permits the addition of hemp and hemp-derived CBD products in food, dietary supplements, and cosmetics, provided the THC concentration is no more than 0.3%. Other states have announced policies that restrict the sale of CBD and/or hemp; in some cases these policies are specific to the addition of hemp or CBD to food and dietary supplements.

Increasingly, however, states are moving to ease restrictions or expressly allow the use and/or sale of hemp and CBD in a broad range of products. A growing number of states are also imposing specific testing and labeling of hemp and CBD products in the absence of clear guidance from FDA on the regulation of these products. While the Roundtable has been actively engaged at the state level to educate state regulators and supports access to safe, regulated hemp and CBD products, the lack of consistent regulation among the states combined with uncertainty at the federal level continue to cause consumer and industry confusion, in particular due to varying labeling requirements.

We believe that a federal regulatory framework, rather than a patchwork of state and local laws, provides the best means for ensuring consumers receive accurate, consistent information about hemp-derived products. Food, dietary supplements, and cosmetics are already subject to a robust legal requirements that prohibit adulterated and misbranded products. Given the well-established safety profile of CBD, additional statutory or regulatory restrictions – whether federal, state or local – are unnecessary. However, FDA has the relevant public health expertise to determine what conditions or limitations, if any, should be in place for foods, dietary supplements, and cosmetics that contain hemp-derived ingredients, rather than having individual states determine what restrictions should be in place for these products.

As indicated above, the labeling of dietary supplements and food could include language that advises consumers to consult with their healthcare professional before using a product that contains hemp-derived CBD, or that recommends against the use of the product by certain populations, e.g., children or pregnant/lactating women, if deemed necessary by the manufacturer/distributor of the products. While many dietary supplement

companies already include such advisories on products labels, in guidance and/or rulemaking FDA could require uniform advisories on all hemp-derived CBD products (food, dietary supplements, and cosmetics).

Summary of Recommendations to FDA:

- FDA should continue to actively enforce the adulteration and misbranding provisions of the FD&C Act to ensure consumers are informed of any risks associated with the use of hemp products.
- Existing federal laws and regulations provide the most appropriate mechanism to inform consumers in a uniform, consistent manner of the potential risks of products that contain hemp-derived ingredients, thereby obviating the need for state restrictions.
- FDA, rather than states, is best suited to determine whether the current labeling of dietary supplements and food containing hemp-derived ingredients should include additional language to inform consumers, in particular vulnerable sub-populations.
- Should FDA determine that advisory language is necessary for products containing CBD or other hemp-derived ingredients, we recommend that FDA consider utilizing the advisory language provided in the U.S. Hemp Authority Guidance.

* * *

Again, we thank FDA for the opportunity to submit these comments. The Roundtable looks forward to working with FDA as it develops its pathway forward for hemp and CBD products.

Respectfully Submitted,

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Attachment 1 - Adverse Event Report Data

Company 1

June 7, 2017 - June 21 2019	Human Product #1 (Full Spectrum)	Human Product #2 (Full Spectrum)	Human Product #3 (Full Spectrum)	Human Product #4 (Full Spectrum)	Human Product #5 (Full Spectrum)	Human Product #6 (Full Spectrum)	Human Product #7 (Full Spectrum)	Vape Product #1 (CBD Isolate)	Pet Product #1 (Full Spectrum)	Pet Product # 2 (Full Spectrum)	Human THC Free* Product #1 (CBD Isolate)	Grand Total
mg per serving	3-5 mg	20-25 mg	20-25 mg	3-5 mg	3-5 mg	20-25 mg	10-15 mg	-	3-5 mg	10-15mg	20-25 mg	
max daily mg	40-45 mg	40-50 mg	40-50 mg	40-45 mg	40-45 mg	40-50 mg	55-60 mg	-	40-45 mg	55-60mg	90-100 mg	
Reaction)	**64**	**44**	**41**	**36**	**35**	**32**	**29**	**20**	**6**	**0**	**1**	**308**
Adverse Reaction)	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0.00%**
Units Sold	**180508**	**34739**	**70520**	**96716**	**60351**	**24197**	**57568**	**17243**	**28326**	**3511**	**7168**	**577336**
AR per SKU	**0.04%**	**0.13%**	**0.06%**	**0.04%**	**0.06%**	**0.13%**	**0.05%**	**0.12%**	**0.02%**	**0.00%**	**0.01%**	**0.05%**
Stomach	23	14	7	6	11	5	7	2	4			**79**
Allergy	10	5	5	8	7	6	9	7				**57**
Headache	9	2	5	6	3	3	2	3				**33**
Nausea	6	6	5	1	7	1	2	2				**30**
Anxiety	7	4	4	5		1	2	2			1	**26**
Felt Strange	3	1	8	1		3	1	1	1			**19**
Burning	1	5	2	4	1	4		1				**18**
Respiratory	2		1		1	3		2				**9**
Acid Reflux		3	1	2	1		2					**9**
Dizzy		2	1		1	2						**6**
Sick	1			1			1		1			**4**
Heart Racing		1			1	2						**4**
Shaky				1			2					**3**
Tingling	1			1								**2**
Mouth Sore			1		1							**2**
Numbness		1			1							**2**
Fatigue	1											**1**
Bladder						1						**1**
Blood Pressure						1						**1**
Eye Twitch							1					**1**
Restless												**0**
Yeast Infection			1									**1**

Company 2 - AER Summary

2018 - 2019	Sprays 1-5mg	Drops 1-7mg	Gum 5-7mg	Supplements 5-30mg	Grand Total
Total AR (Adverse Reaction)	**144**	**226**	**1**	**252**	**623**
Total SAR (Serious Adverse Reaction)	**0**	**0**	**0**	**0**	**zero**
Units Sold	**314,309**	**380,435**	**14,370**	**713,311**	**1,422,425**
AR rate per category	**0.05%**	**0.06%**	**0.01%**	**0.04%**	**0.04%**

Company 2 - Raw Data

	1-3 mg CBD Spray; 128,479	3-5 mg CBD Drops; 91,168	3-5 mg Spray; 74,390	1-3 mg CBD Spray; 68,865	3-5 mg CBD Drops; 74,390	5-7 mg CBD Drops; 79,004	15-20mg CBD Softgels; 149,645	3-5 mg CBD Spray; 33,020	5-7 mg CBD Drops; 52,226	15-20 mg CBD Supplement; 5,624	10-15 mg CBD Capsules; 72,405	10-15mg CBD Caps; 88,717	15-20 mg CBD Supplement; 4,638	1-3 mg CBD Spray; 3,565	15-20mg CBD Softgels; 119,998	10-15 mg CBD Supplement; 2,724	15-20mg CBD Softgel ; 72,405	15-20 mg CBD Supplement; 5,657	3-5 mg CBD Drops; 12,022	5-7mg CBD Supplement; 17,303	3-5mg CBD Spray; 5,990	1-3 mg CBD Drops; 21,511	5-7 mg CBD Gums; 14,370	5-7 mg CBD Drops; 8,649	5-7 mg CBD Softgels; 16,326	15-20mg CBD Capsules; 104,200	1-3 mg CBD Drops; 15,822	5-7mg CBD Supplement; 9,259	1-3 mg CBD Drops; 18,045	5-7mg CBD Supplement; 10,677	5-7 mg CBD Softgels; 20,019	3-5 mg CBD Drops; 7,598	25-30mg CBD Capsules; 10,429	10-15 mg CBD Supplement; 3,285	TOTAL
Product ID	102	95	104	103	94	96	107	105	97	187	106	137	189	22	140	188	184	151	327	334	25	326	333	311	148	141	310	335	309	336	183	312	163	154	
abdominal discomfort	4	12	5	7	11	6	5	1	6	0	6	12	1	0	2	0	4	0	2	3	1	1	0	1	1	1	0	0	1	0	1	0	1	0	95
malaise	7	5	2	6	3	2	6	1	2	0	3	6	0	2	0	0	0	1	0	0	1	0	0	0	1	0	1	0	1	0	1	0	0	0	51
headache	6	3	4	2	4	4	4	2	6	0	3	2	0	0	2	0	1	0	0	0	1	2	1	0	0	2	0	0	0	0	0	0	0	0	49
hypersensitivity	3	8	2	2	5	1	6	1	2	0	3	2	1	0	0	0	0	0	1	1	0	0	0	1	0	1	2	0	0	0	0	0	0	0	42
dyspepsia	2	2	4	0	4	2	1	1	2	0	5	2	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	30
adverse reaction	1	2	2	1	2	1	6	0	1	0	1	2	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	21
lack of effect	1	3	5	0	2	1	4	1	1	0	1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	21
nausea	2	4	1	1	2	2	1	0	7	0	3	1	0	0	3	0	2	1	0	0	0	0	0	0	1	0	0	1	0	1	1	0	0	0	34
feeling abnormal	1	0	1	2	2	0	1	0	1	0	1	1	0	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	13
pruritus	0	1	1	0	1	1	0	1	3	0	1	1	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12
dermatitis	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
rash	1	2	1	0	1	0	1	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
urticaria	1	1	0	1	1	0	0	0	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
anxiety	1	1	2	2	2	0	4	1	2	1	3	1	1	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	23
gastrointestinal disorder	1	1	1	0	0	2	2	0	0	0	3	0	0	0	2	0	2	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	16
somnolence	1	0	0	0	1	0	2	0	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
heart rate increased	0	0	0	1	1	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	6
feeling anxious	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
dizziness	1	1	1	0	0	0	1	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	8
hypertension	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	4
flushing	0	1	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4
canker sores	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	4
diarrhea	0	1	1	0	0	1	0	0	1	0	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
gastroesophageal reflux	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
feeling jittery	0	0	0	0	0	0	0	0	0	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
anxeity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
insomnia	2	0	0	0	1	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	6
Abdominal pain	0	1	0	0	0	2	1	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6
oropharyngeal pain	1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
abnormal dreams	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
tinnitus	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
hyperactivity	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
paresthesia	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
blood pressure increased	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
depression	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
disorientation	2	0	0	0	0	0	1	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	6
drug-supplement interaction	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
euphoria	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
lethargy	1	1	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
gingivitis	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
decreased efficacy	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
asthma exacerbation	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
syncope	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
oral pain	1	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
medication interaction	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
eructation	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
stomatitis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
burning sensation	0	1	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
pharyngitis	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
vision blurred	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
lucid dreaming	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
dysgeusia	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2

hyperalgesia	0	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4
emesis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Ocular pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Generalized Rash	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Constipation	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3
Epistaxis	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
hypotension	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
oral canker	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
conjunctivitis	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
migraine	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2
pharyngeal pain	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
restless legs	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
cystitis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
xerosis	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
arthralgia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
suicidal ideation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
gastritis	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
pre-syncope	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
nightmares	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
palpitations	0	1	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
lightheadedness	0	0	0	1	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
arrhythmia	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
gum hemorrhage	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
discoloration mouth	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
liver function test abnormal	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
dyspnea	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
agitation	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
influenza-like illness	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
swelling	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
tongue discoloration	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
paresthesia oral	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
dehydration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
bullae	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
rash	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
throat swelling	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
hallucinations	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
fatigue	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
pain increased	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
felt abnormal	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
malaise	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
allergy	0	1	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4
twitching	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
vomiting	0	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	5
peripheral swelling	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
visual disturbance	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
sleep disturbance	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
pharyngeal discomfort	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Mental Status change	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
paresthesis oral	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
abdominal distension	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
confusion	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
sneezing	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
edema	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
paranoid thoughts	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
discoloration teeth	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
skin discoloration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
chest pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1
chest tightness	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
swelling mouth	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
contact dermatitis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
excessive phlegm	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
erythema	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
abnormal thinking	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
borborygmi	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
enuresis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

nasal congestion	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
interaction with medication	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
flatulence	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
dysphagia	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
muscle spasms	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
TOTAL	49	72	41	32	56	29	72	12	44	2	49	51	6	6	22	3	16	4	4	4	4	3	1	9	7	5	4	1	4	2	5	1	1	2	**623**

Summary of Data Provided

This data captures complaints / adverse events reported for products sold during the period of **1/1/18 through 6/29/19**. We are a large hemp extract company and sold several hundreds of thousands of units of our hemp extract products during this period. Below is the percentage of complaints / adverse events reported during this period that were related to human ingestion or topical application of our products (exclusive of complaints solely related to the customer not liking the taste of ingestibles or texture of topicals). Complaints not related to actual ingestion or topical application (*e.g.* shipping, order issues, etc.) are not included in this data.

Product Description	Complaint/AE Percentage of Units Sold	Complaint / Adverse Event Descriptions
Hemp Extract MCT Tincture, 300mg CBD, C	0.014%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of allergic reaction, stomach pain, "feeling badly," and a side effect
Hemp Extract MCT Tincture, 100mg CBD, C	0.000%	None
Hemp Extract MCT Tincture, 3600mg CBD, C	0.109%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of nausea, feeling sick, and "feeling badly"
Hemp Extract MCT Tincture, 300mg CBD, N	0.027%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of headaches, upset stomach, "feeling worse," "bad effect," and dissatisfaction
Hemp Extract MCT Tincture, 100mg CBD, N	0.000%	None
Hemp Extract MCT Tincture, 3600mg CBD, N	0.060%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of feeling sick, not feeling well, and a side effect
Hemp Extract VG Tincture, 300mg CBD, G	0.014%	Isolated incident of indigestion
Hemp Extract VG Tincture, 600mg CBD, G	0.043%	These minimal complaints were due to isolated incidents of stomach issues and hives
Hemp Extract VG Tincture, 300mg CBD, N	0.000%	None
Hemp Extract VG Tincture, 600mg CBD, N	0.024%	Isolated incident of headaches
Hemp Extract Powder Blends, 175mg CBD, M	0.000%	None
Hemp Extract Powder Blends, 300mg CBD, B	0.000%	None
Hemp Extract Powder Blends, 150mg CBD, CC	0.000%	None
Hemp Extract Powder Blends, 300mg CBD, C	0.000%	None
Hemp Extract Liposome, 1000mg CBD	0.038%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of upset stomach and "health problems"
Hemp Extract Liposome, 300mg CBD	0.010%	These minimal complaints were primarily due to no effect with an isolated incident of severe headaches
Hemp Extract Liposome, 100mg CBD	0.000%	None
Hemp Extract Metered Dispenser, 1000mg CBD	0.000%	None
Hemp Extract Capsules, 450mg CBD	0.038%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of feeling tired, dizziness, "feeling badly," a bad reaction, the product not working as expected, and no effect with "additional problems"

Product Description	Complaint/AE Percentage of Units Sold	Complaint / Adverse Event Descriptions
Hemp Extract Capsules, 900mg CBD	0.031%	These minimal complaints were primarily due to no effect with nominal or isolated incidents of dizziness, stomach pain, diarrhea, "feeling badly," no effect plus feeling sick, and a bad rash with small blisters at the top of customer's feet
Hemp Extract Balm, 125mg CBD	0.005%	Isolated incidents of no effect and a bad reaction
Hemp Extract Balm, 250mg CBD	0.000%	None
Hemp Extract Lip Balm, 5mg CBD	0.000%	None

Company 4

June 2017-June 2019	Oil 7-60 mg	Capsules 15-35 mg	Gummies 10mg	Topicals	Grand Total
Total AR (Adverse Reaction)	**200**	**16**	**2**	**2**	**220**
Total SAR (Serious Adverse Reaction)	**0**	**0**	**0**	**0**	**zero**
Units Sold	**1,397,030**	**331,187**	**14,043**	**478,458**	**2,220,718**
AR rate per category	**0.01%**	**0.00%**	**0.01%**	**0.00%**	**0.01%**

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 or 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.