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## Veterinary Pet Supplements and Nutraceuticals

**Carrie J. Finno, DVM, PhD, Diplomate ACVIM**

Department of Population Health and Reproduction, School of Veterinary Medicine, University of California, Davis CA USA 95616

### Abstract

Veterinary pet supplements and nutraceuticals are widely used by dog, cat and horse owners across the United States, generating millions of dollars in revenue for manufacturers. Despite the widespread use of these veterinary products, oversight and regulation remain limited as compared to human dietary supplement regulations. This review describes the current regulation, quality control, safety and efficacy of pet supplements and nutraceuticals targeted towards the dog, cat and horse.

### Introduction

It is estimated that between 10–33% of dogs and cats<sup>1</sup> and up to 84% of horse owners<sup>2</sup> in the United States are fed a pet supplement or nutraceutical. In 2016, sales of pet supplements were estimated at \$580 million, up 3.5% from the previous year.<sup>1</sup> Despite this widespread use and economic impact, supplements intended for companion animals (i.e. not food animals for human consumption) do not fall under the Dietary Supplement Health and Education Act (DSHEA) of 1994 and therefore undergo less regulatory oversight than human dietary supplements.

### FDA Regulation

The FDA Center for Food Safety and Applied Nutrition (CFSAN) regulates the safety of dietary supplements in humans. The term “dietary supplement” is defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994, as a product taken by mouth *in humans* that contains a “dietary ingredient” intended to supplement the diet. The “dietary ingredient” can include vitamins, minerals, herbs or other botanicals, amino acids and substances such as enzymes, organ tissues and metabolites.<sup>3</sup> Therefore, the term “dietary supplement” should only be applied to products intended for human use. By contrast, products termed human “nutraceuticals” were defined in 1989 as a “food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease”.<sup>5</sup> There is, however, no regulatory definition through FDA for nutraceuticals.

Another branch of the FDA, the Center for Veterinary Medicine (CVM), is responsible for the regulation of animal food products. The CVM has mechanisms for food additive approval, which apply to any product unless it is generally recognized as safe for that

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Corresponding author: Carrie J. Finno, DVM, PhD, University of California, Davis SVM, Room 4206 Vet Med 3A, One Shields Ave, Davis, CA 95616, (530)-752-2739, cjfinno@ucdavis.edu.

intended use (i.e. forages, grains and most mineral and vitamins). This regulation applies to animal food additives that could affect the target animal's safety. Under Section 201(s) of the FD&C Act, the definition of a food additive *does not* include any ingredient in or intended for use in a dietary supplement.<sup>4</sup> Although the dietary ingredient used in the dietary supplement must not adulterate the supplement, it does not have to be Generally Recognized As Safe (GRAS) for its intended use in the supplement.<sup>4</sup> However, non-dietary ingredients (binders, fillers, etc.) are not exempt from the food additive definition. If any product claims to cure, treat, prevent or mitigate disease, the product should be considered a “new animal drug”. Pet food, including pet treats but not pet supplements, falls under the Association of American Feed Control Officials (AAFCO) and is tightly regulated on a federal and state level.

FDA-CVM compliance policy guide section 690.100 specifically addresses the regulation of nutritional supplements for companion animals. The policy states that the CVM will “not generally object to the marketing of nutritional supplements for oral administration to companion animals provided they conform to the following restrictions, (1) there is a known need for each nutrient ingredient represented to be in the product...,(2) the label represents the product for use only in supplementation and not as a substitute for good daily rations, (3) the product provides meaningful but not excessive amount of each of the nutrients that is represented to contain, (4) the labeling should bear no disease prevention or therapeutic, including growth promotional, representations, (5) the labeling should not be otherwise false or misleading in any particular, and (6) the product is neither over-potent nor under-potent nor otherwise formulated so as to post a hazard to the health of the target animal.”

Companies can, however, incorporate claims of improving “health” on the labeling of food animal products (i.e. “dental health”, “hairball control”). While CVM may take appropriate regulatory action against products that violate this policy, a standardized monitoring system is not currently in place.

The FDA uses the Nutritional Requirements of Domestic Animals, a standard test published by the National Academy of Sciences-National Research Council (NAS/NRC), to arrive at a standard level of supplementation.<sup>14</sup> The NAS/NRC defined a pet supplement as “a substance for oral consumption by horses, dogs and cats, whether in or on feed or offered separately, intended for specific benefit to the animal by means other than provision of nutrients recognized as essential or for provision of essential nutrients for intended effect on the animal beyond normal nutritional needs, but not including legally defined drugs.”

For now, AAFCO only regulates labeling of “food-type” supplements, although it will monitor for any ingredient misrepresentation of all animal supplements. Seven states, including Texas, Oregon, Michigan, North Dakota, South Dakota, Virginia and Wyoming have enacted “remedy laws” to regulate pet supplements that do not qualify as “foods” according to the AAFCO definition.

**Call out: Do you know if or how those supplements you give your dog, cat or horse are regulated?**

**Other Regulatory Councils**—Veterinary product jurisdiction was, for a long time, the responsibility of the North American Veterinary Nutraceuical Council (NAVNC), formed in

1996 (and now defunct), to promote and enhance the further quality, safety and long-term effectiveness of nutraceuticals used in veterinary medicine. The NAVNC defined a nutraceutical as a “nondrug substance that is produced in a purified or extracted form and administered orally to provide agents required for normal body structure and function with the intent of improving the health and well-being of animals”.<sup>5</sup> In 1996, the American Veterinary Medical Association provided guidelines on the use of nutraceuticals, whereby the therapeutic use of micronutrients, macronutrients and other oral nutritional substances is permitted, although veterinarians should be aware of the ingredient and content and their benefits, bioavailability, efficacy and safety. Also, the American Association of Equine Practitioners (AAEP) endorses this statement for horses (<https://aaep.org>).

The National Animal Supplement Council (NASC) was formed in 2001 as a nonprofit industry group that aims to place safety standards on supplements for companion animals and horses and on the manufacturers to promote the use of safe ingredients on their products. The NASC Quality Seal Program awards a seal to those manufacturers that meet the organizations’ standards (<https://nasc.cc/nasc-seal>). However, NASC does not require companies to perform efficacy studies on their products or verify that scientific research data are available proving product efficacy. Additionally, there is no incentive for companies to have their products tested without any mandated oversight. The American College of Veterinary Nutrition (ACVN) does not have a position on pet supplements, but the frequently asked questions section of the ACVN website states, “If your pet is eating a complete and balanced commercially available pet food, supplements are not recommended unless specifically prescribed by your veterinarian” (<https://acvn.org/frequently-asked-questions/>).

Therefore, veterinarians are advised by their governing body to be cognizant of content, efficacy and safety of these products. With the paucity of well-controlled systemic reviews for these products,<sup>6</sup> this is a daunting task. Perhaps even more concerning is that a veterinarian is legally liable if he or she recommends a pet supplement or nutraceutical product that leads to adverse effects.<sup>7</sup>

## Types of Pet Supplements

In dogs and cats, the most popular supplements include joint and digestive health supplements, followed by supplements to aid with cognition, skin/coat and heart health.<sup>1</sup> In cats, hairball control supplements remain high in demand, followed by cat-specific supplements for urinary tract infections and kidney disease.<sup>1</sup> “Pet supplements, with the addition of turmeric/curcumin, demonstrated to have some anti-oxidative and anti-inflammatory effects in humans,<sup>8,9</sup> have gained popularity as joint supplements.<sup>1</sup>

In performance horses, a recent survey in the United Kingdom identified joint and mobility supplements were the most commonly used for eventing and behavioral supplements for dressage.<sup>10</sup> In the United States, horse owners use supplements to either treat, or more commonly, to prevent a perceived issue. For example, 57% of surveyed horse owners used joint supplements to treat osteoarthritis whereas 90% of horse owners administered these supplements to prevent joint disease. Likewise, 43% of owners used hoof supplements as a

“therapeutic” whereas 83% administered them as a preventative measure.<sup>2</sup> Additional supplements commonly used in horses include digestive aids, including pro- and prebiotics and those designed to prevent or resolve gastric ulcers; biotin, methionine and zinc to promote hoof growth; omega-3 fats for coat; and thiamine, magnesium, L-tryptophan, valerian and chamomile for behavioral effects. Most of these products have not undergone any well-designed efficacy trials in horses and “suggestive” data is often extrapolated from studies in other species. Notably, 58% of horse owners surveyed in the United States spend \$30 or more per month on horse supplements, with 15% spending over \$90/month. Despite this financial investment, only 50% of horse owners perceived supplements as “safe”.<sup>2</sup>

## Quality

While there exists a mechanism through the FDA CVM to regulate pet supplements if there is an adverse event, there is no regulatory mechanism to ensure that a manufacturer is accountable for the labeling of a novel ingredient in pet supplements or nutraceuticals. As such, manufacturers should be asked about the accuracy of their labels and all aspects of their manufacturing program, with an emphasis on which “Good Manufacturing practices” (GMPs) are followed. For example, chondroitin sulfate (CS), an expensive ingredient derived from shark and bovine cartilage, was found to be inappropriately labeled in 84% (9/11) of products in a study partially funded by Nutramax Laboratories.<sup>11</sup> The amount of mislabeling ranged from 0–115%. In another study of five glucosamine, five CS and one combination equine products, the actual composition of GLN was 63.6% to 112.2% of the label claim whereas the concentration for CS ranged from 22.5%–155.7%.<sup>12</sup>

The National Science Foundation (NSF) certifies human dietary supplements against NSF/ANSI 173 using GMPs. NSF conducts independent, third-party testing of dietary supplements. As only quality is tested, this certification could be extended to pet supplements. Consumer Laboratory (<http://www.Consumerlabs.com/>) is a for-profit laboratory that offers a seal of “validation” for pet and dietary supplements sold in the USA that are appropriately labeled. [ConsumerLab.com](http://www.ConsumerLab.com) selects products for testing and validation. In addition, through their voluntary Quality Certification Program, manufacturer and distributors can request testing of their products for a fee. In response to these requests, [ConsumerLab.com](http://www.ConsumerLab.com) will purchase products on the market and test and evaluate them just like others. Results are released directly to the manufacturer and will only be posted to the website if “approved” by the manufacturer. The public can access selected information from the [ConsumerLab.com](http://www.ConsumerLab.com) website for a fee (\$20 annual at the time of this printing) for ingredients that have been tested. Criteria for passing and failing and reasons for failure for specific ingredients can be accessed, as can a list of proprietary products that have passed. [ConsumerLab.com](http://www.ConsumerLab.com) will provide its top picks based on their independent product testing and validation. It is worth repeating, however, that [ConsumerLab.com](http://www.ConsumerLab.com) is not evaluating the efficacy of any particular supplement.

At this time, ingredients studied by [ConsumerLab.com](http://www.ConsumerLab.com) for animals include joint supplements (glucosamine, chondroitin sulfate, methylsulfonylmethane (MSM) and Boswellia), omega-3 and omega-6 fatty acids and multivitamins. Within the joint supplement category for animals, of the four joint products for dogs and cats that were

evaluated by [ConsumerLab.com](https://www.consumerlab.com), only two were approved for their quality. [ConsumerLab.com](https://www.consumerlab.com) also has a voluntary Quality Certification Program, in which four additional dog and cat joint products were approved. Within the omega fatty acid supplement category, one out of two supplements was approved, with the not approved supplement containing adequate omega-3s and omega-6s but only 62.5% of the listed amount of omega-9s. At this time, there are no equine supplements that have been evaluated by Consumer Laboratories.

Pet supplements should not carry a “Supplement Facts” panel as they are unable to comply with the labeling regulations, specifically the declaration of nutrients with Daily Values.

## Safety

A survey conducted in 2018 demonstrated a high level of confidence (87%) in the safety, efficacy and quality of *human* dietary supplements consumed by adults in America. Additionally, 78% of Americans perceive the dietary supplement industry as being trustworthy.<sup>13</sup> In contrast, a recent survey of horse owners identified that only 45% of owners believed that it was safe to administer supplements to their horses despite the fact that 84% of respondents gave supplements to at least one horse they owned.<sup>2</sup>

In 2014, the National Research Council (NRC) performed an extensive review to evaluate the safety of three pet supplements in horses, dogs and cats – lutein, evening primrose oil and garlic.<sup>14</sup> NRC determined that there was lack of quality safety data available for these three supplements and instead reported only the historical safe intakes (HSI) and estimated a presumed safe intake (PSI). Lutein is purported to act as an antioxidant and treat age-related macular degeneration in humans. Evening primrose oil is made up of fatty acids and purported to maintain normal health and metabolism. Garlic has been touted to reduce the risk of cardiovascular disease and cancer and stimulate the immune system. Based on the paucity of safety data available, the NRC provides only HSI and PSI values for these three products in this evaluation.

While the FDA has approved food additives permitted for direct addition to food for human consumption that include many common dietary supplements, this dataset *does not* apply to companion animals.<sup>15</sup> While FDA-CVM requests reporting of adverse effects from the feeding of pet supplements, it is worth noting that the lack of reported side effects does not mean that a product is safe, especially with long-term use. As an example of species-specific safety concerns, while garlic is considered safe in humans, excess garlic can cause hemolytic anemia in horses, dogs and cats.<sup>16</sup> Many herbs that are purported to provide beneficial effects when used in small doses in humans are toxic to dogs, cats and horses.<sup>17</sup> For example, herbs touted as immune stimulants can contain toxic pyrrolizidine alkaloids, which horses are particularly sensitive to. The risk of herb-drug interactions should also be considered. Pharmacokinetic interactions include those that alter the absorption, metabolism, distribution or elimination of a drug whereby pharmacodynamics interaction at particular receptor sites can be agonistic or antagonistic. Non-steroidal anti-inflammatory drugs combined with herbs that may have anti-platelet effects, including ginkgo, ginger, ginseng and garlic, may increase bleeding risk.<sup>17</sup> Adverse reactions in 47 dogs, including death in 8,

occurred following ingestion of a weight loss supplement containing guarana (caffeine) and ma huang (ephedrine).<sup>18</sup>

### **Call out: Some ingredients that are safe for humans are not for animals**

If there is concern about the nutrient content or substances added to a pet supplement, consumers can request independent analysis of supplements prior to purchase and should consult with their veterinarian. As mentioned previously, veterinarian is legally liable if he or she recommends a supplement or nutraceutical product that leads to adverse effects.<sup>7</sup>

## **Efficacy**

Claims of efficacy for many pet supplements and nutraceuticals are often based on subjective methods of assessment, including owner testimonials, which have not been rigorously tested in well-designed clinical trials and published in peer-reviewed journals, and should therefore be viewed with skepticism. While valuable for cross-species comparisons, results extrapolated from studies performed in humans or rodent models do not take into account the differing pharmacokinetics and pharmacodynamics among species. Additionally, many pet supplements and nutraceuticals are consumed orally, and oral bioavailability of drugs varies widely across species. Consumers should also be advised to be skeptical of marketing claims based on *in vitro* work. For example, many proposed benefits of pet joint supplements are based on *in vitro* work, which often relies on very high doses directly applied to cartilage explants or cultured chondrocytes.<sup>19</sup>

In human medicine, systematic reviews and standardized reporting have been implemented for drug interventions in order for practitioners to obtain a summary of selected quality scientific information upon which they can base their decisions.<sup>20</sup> This is much more difficult to conduct for nutritional intervention in humans. Systematic reviews are still uncommon in veterinary medicine for drug interventions and virtually nonexistent for pet supplements or nutraceuticals. One well-designed systematic review of the efficacy of nutraceuticals for osteoarthritis was performed in 2012, evaluating 22 papers across horses, dogs and cats.<sup>6</sup> The strength of evidence was low for all nutraceuticals except for omega-3 fatty acid in dogs. Green-lipped mussel powder (GLMP) had a significant effect in 3 of 4 studies<sup>21–24</sup> but was inconsistent between studies, precluding a strong indication for clinical use.<sup>6</sup> The authors of this review propose that, “Once a nutraceutical has been suggested to be effective in one group, conditions of administration should be defined if the purpose is to assess whether it is also effective in another group or compare it with another product.”<sup>6</sup>

Pet supplements for animals, as for humans, is to augment a diet lacking nutrient density to meet animal needs, generally for maintenance, growth, pregnancy or lactation. A supplement can supply additional vitamins that may be lacking in an animal’s diet. For example, horses that do not have access to fresh pasture typically require supplementation with a bioavailable formulation of vitamin E, which is not found in grain or hay.<sup>25</sup> Studies have been performed comparing various equine vitamin E formulations and identified that the most bioavailable form of vitamin E is a water-dispersible “RRR” alpha-tocopherol formulation.<sup>26,27</sup> Initial studies have been consistently validated,<sup>28</sup> providing strong evidence for veterinarians to recommend particular products and dosages.

Guidelines have been established for the application of evidence-based medicine to veterinary clinical nutrition.<sup>29</sup> Grades of evidence were rated from I (highest; data obtained from at least 1 properly randomized, controlled clinical trial using the targeted species that developed the disease naturally) to IV (opinions, descriptive studies, studies conducted in other species or reports of expert committees). These same authors then applied these guidelines in an evaluation of pet supplements and nutraceuticals for the management of obese and overweight pets.<sup>30</sup> Of the products evaluated, only one (dietary L-carnitine supplementation) met Grade 1 evidence for weight loss in cats, as previously defined.<sup>29</sup>

## Conclusion

While the amount of scientific information on veterinary pet supplements and nutraceuticals is increasing, there remains a paucity of quality control, safety and efficacy data for the majority of both the substances marketed in pet supplements and the resulting products for purchase currently available. Despite this lack of evidence, the use of veterinary supplements and nutraceuticals continues to increase. Veterinarians and animal owners should encourage increased enforcement of regulations of these products and demand that manufacturers work with researchers to fund and perform well-controlled clinical trials to determine safety and efficacy. It is proposed that these studies should include (1) independent evaluation of product contents, (2) a well-defined blinded and randomized study design with placebo controls and an effective sample size, (3) detail provided to allow for replication and no additional treatment provided, (4) accurately reported statistical analyses and (5) conflicts of interest and funding sources (including supplement manufacturer) declared. Once efficacy of a product has been determined, this should be replicated by independent groups to ensure validity. Unfortunately, with the limited regulation of veterinary pet supplements and nutraceuticals, claims on pet supplements require further substantiation through increased research and enhanced regulatory oversight.

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**Fig. 1.** Horses receive their daily intake of vitamin E from fresh green pasture. For horses without pasture access, targeted vitamin E supplementation may be necessary.