

PRODUCT/HEALTH CLAIMS

Health Claims

- For animals, the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) regulates two classes of products: food and drugs. Depending on the intended use, an animal dietary supplement is considered either a food or drug. There is no separate category for “supplements” for animals. ¹
- In the Dietary Supplement Health and Education Act (DSHEA) of 1994, the term “dietary supplement” was defined but it did not specify if the definition applied to humans, animals, or both. The main effect of DSHEA was to reclassify certain dietary ingredients from regulation as food additives, which require pre-market approval. ²
- In 1996, CVM published a notice in the Federal Register to explain that DSHEA did not apply to animal products. ¹
- Simply, federal laws and regulations do not recognize a category of products for animals called “dietary supplements.” Depending on the stated intended use, the product is either a food or drug, regulated by the FDA. ¹
- Many owners purchase products intended for human use for their pets. It is important to know that manufacturers of human dietary supplements do not have to provide FDA with evidence that their dietary supplements are effective or safe. However, they are not permitted to market unsafe or ineffective products. ²
- Once a human dietary supplement is marketed, the FDA has to prove that the product is not safe in order to restrict its use or remove it from the market. ²
- In contrast, before being allowed to market a drug, manufacturers must obtain FDA approval by providing convincing evidence that it is both safe and effective. ³
- Some supplements that are safe for humans can be toxic to dogs or cats. **Therefore, it is imperative that pet owners consult with their veterinarians before giving a dietary supplement to their pet.**

FDA Restrictions:

Generally, the Center for Veterinary Medicine CVM will not 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 for each animal for which the product is intended.
2. The label represents the product for use only in supplementation of, and not as a substitute for, good daily rations.
3. The product provides a meaningful but not excessive amount of each of the nutrients it is represented to contain.
4. The labeling should bear no disease prevention or therapeutic representations, including growth promotion.
5. The labeling should not be otherwise false or misleading.

6. The product is neither over-potent nor under-potent nor otherwise formulated so as to pose a hazard to the health of the target animal.

Claims Regulation:

Because CVM has determined that DSHEA does not apply to animal supplements, many claims that are permitted for human dietary supplements are not permitted for animal supplements. CVM categorizes ingredients in animal supplements as one of two types: 1) a nutritional ingredient (intended to provide nutrition), or 2) a non-nutritive ingredient (does not provide nutrition).

❖ **Claims on animal feed products (including animal supplements)** that establish the intended **use** of the product **to affect the structure or function of the body of animals** in a manner other than via nutrition, aroma or taste causes the product to be a drug.

❖ Claims that an **animal supplement** affects the structure or function of the body based on its **nutritive value (a nutritional ingredient)** is considered a food claim, and the product **will be categorized as a food**.

❖ Claims that an animal supplement affects the structure or function of the body apart from its nutritive value (a non-nutritive ingredient) is considered a drug claim, and the product will be categorized as a drug.

❖ Moreover, claims for 1) improved or increased production and performance, 2) alteration or improvement in function, or 3) treatment or prevention of disease are also considered drug claims, regardless of whether the ingredient is nutritive or non-nutritive. FDA has explicitly stated that pet supplements should not “bear such vague therapeutic suggestions as promotion of ‘health,’ ‘stamina,’ ‘strength,’ or that they are of any special value for breeding purposes or for show or racing purposes or for working animals, or that by virtue of their formulation [i.e., ‘chelated,’ ‘timed release,’ ‘natural’] they are superior to the ordinary vitamin-mineral preparations of commerce.”

National Animal Supplement Council (NASC)

NASC member companies are required to demonstrate compliance with the following criteria before they are granted permission to display the NASC Seal on their products.

1. The company must have a **Quality Manual** in place that provides written Standard Operating Procedures for production process control.
2. The company must have an **Adverse Event Reporting/Complaint System** in place to continually monitor and evaluate products.
3. They must follow proper **label guidelines** for all products.

4. The company must include any **specific warning and cautionary statements** recommended by the Food & Drug Administration's Center for Veterinary Medicine and the NASC Scientific Advisory Committee.

We are dedicated to educating and revolutionizing the nutritional supplement marketplace. Dr. Roger Kendall, Vice President of Research and Development, and Dale Metz, CEO of Food Science Corporation, are founding members of the National Animal Supplement Council. Dale Metz is the Vice President of the NASC and on the Board of Directors. He is also involved in direct meetings with the FDA to establish new guidelines to be issued by the FDA for the animal dietary supplements. Dr. Roger Kendall is the Chair of the NASC Scientific Advisory Committee.

NASC is committed to the production and distribution of high quality supplements for non-human food chain animals and holding member companies accountable NASC guidelines.

What is an animal health supplement?

A product intended to support maintenance of normal biological structure and function in animals which are not intended for human consumption, such as dogs, cats and horses. These types of products **are also called dosage form animal health products**. Joint support products containing glucosamine, chondroitin sulfate or MSM are examples of animal health supplements.

How are animal health supplements regulated?

Most animal health supplements are considered "drugs of low regulatory priority" and are regulated by the Food and Drug Administration (FDA). If the product is intended as a source of minerals and vitamins for a non-human food chain animal (dogs, cats and horses), it is classified as a nutritional or feed supplement and regulated by the FDA and individual state feed control officers through the AAFCO Model Bill. Most states follow the recommendations of the Association of American Feed Control Officials (AAFCO).

What are labeling standards?

NASC developed label templates and advertising standards in accord with FDA/CVM input with the intent of helping consumers better understand the use of these products in maintaining and promoting the health of animals. NASC members must abide by such guidelines or be subject to fines and expulsion from the organization.

Why is NASC membership important?

Membership is important to all who promote the use of animal health and nutritional supplements to support animal well-being and vitality. It provides a cohesive and consistent platform from which to address regulatory issues and ensure that these products continue to be available and meet consistent quality standards. **Membership ensures a voice in the oft quoted grey area of "supplements – not a drug and not a feed."** NéVetica is a member of the **National**

Animal Supplement Council (NASC). Remember, not to use the following words when describing our relationship with the NASC: partners, partnered with, or backed by the NASC.

APPENDIX I

Proposed Guidance for NASC Members

EXAMPLES OF PROPOSED NASC CLAIMS BY PRODUCT CATEGORY

Structure/Function Claims, Appendix I-II Confidential – NASC © 2017 Document Control Number 1.13.3

Source and Purpose of Appendix I & II

The claims in Appendix I & II were compiled following a request by the Food and Drug Administration, Center for Veterinary Medicine. They are provided to NASC Members as examples of claims which may be allowable or not allowable for Dosage Form Animal Health Products and/or Animal Feed/Food Supplements.

THIS IS NOT AN EXHAUSTIVE OR COMPREHENSIVE LIST AND IS PROVIDED FOR GUIDANCE ONLY.

All claims should be “truthful, substantiated and not false or misleading.” Claims for animal feed/food products should also be nutritionally linked to the approved feed ingredients in the product with supporting documentation available if requested.

Below are some suggestions for Dosage Form Animal Health Products

APPENDIX II

Words that should be used:

- Support
- Maintain
- Promote

Good qualifiers and modifiers:

- May, May help, Help
- Occasional
- Seasonal

Words that should NOT be used:

- Treat, prevent, cure, mitigate and similar overt or implied disease claims
- Use of any disease name or reference to a disease
- Any express or implied comparison to drugs
- Chronic

Words that are red flags and should be used WITH CAUTION , although they may be used in the proper context on dosage form products:

- Relieve
- Aids
- Enhance
- Improve
- Increase
- Boost
- Decrease
- Reduce
- Inflammation, Inflammatory