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# *Animal* **JOINT HEALTH**

Overview of research and trending ingredients for companion pet, equine joint health products

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# Regulatory Update, Claims For Animal Supplements, and Important Changes

by William Bookout

## INSIDER's Take

- There are regulatory limitations surrounding production similar to “dietary supplements” for animals.
- All animal supplements marketed as food (nutritionals) fall under FSMA rules.
- Many commonly utilized ingredients are not approved for nutritional purposes in animals.

[Since my last update](#), companies continue to explore the area of products similar to “dietary supplements” for animals, but may not understand regulatory limitations surrounding these products. Under current U.S. law, only two legal categories exist for animal products that are similar to human dietary supplements: animal food/feed, and animal drugs.

Categorically—meaning legally—there is no other choice.

Most people are unaware of this reality for animal supplements, and also don’t know that many commonly utilized ingredients are not approved for nutritional purposes in animals. Examples of ingredients unapproved for animal food, but often found in joint products, include glucosamine, chondroitin sulfate and methylsulfonylmethane (MSM), and virtually all herbal ingredients if included for purposes other than flavorings.

The Federal Food, Drug and Cosmetic Act (FD&C) defines food (animal feed) and a drug as:

**Food**—“articles used for food or drink for man or other animals ... and articles used for components of any such article.” There is no requirement that animal foods have pre-market approval by FDA Center for Veterinary Medicine (CVM). The act does require animal foods, like human foods, to be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled.

**Drug**—“an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article intended to affect the structure or function of the body other than food.” In this definition, the courts have interpreted “food” to mean something providing nutrition, taste or aroma. If a food affects the structure or function of the body, it does so by these properties (e.g., a food may provide nutrients such as calcium for proper bone structure). However, if a substance affects the structure or function of the body apart from its nutritive value, such as improving joint function, it may be considered a drug. Structure/function effects extending beyond the “food” umbrella include claims for improved or increased production and performance, and alteration or improvement in function.

Does this mean that similar products for animals cannot be sold? No, but it does mean companies should understand the regulatory landscape and be mindful of how

to responsibly market these products. U.S. law states that intended use of the product, as established by label claims, determines where the product falls categorically. Criteria also requires claims to be truthful and not false or misleading to the consumer, and substantiated.

Given these criteria, the National Animal Supplement Council (NASC) suggests the following guidance for animal supplement claims:

**Nutritional (food) products**—structure claims may be allowed provided the above criteria is met and the claim is nutritionally linked.

Examples:

“A complete and balanced diet with the proper calcium:phosphorous ratios help support strong bones and teeth.”

“Essential fatty acids help support a healthy, glossy coat.”

“Probiotics help maintain healthy digestion.”

**One may think since human dietary supplements weren't included in the Food Safety Modernization Act (FSMA) legislation, animal supplements would also be excluded. This is not the case.**

Any claims, either overt or implied, suggesting “improvement” may face objection and could result in disruption to business. It's important to remember products for animals are potentially regulated at both the federal level by FDA-CVM and also state regulatory agencies.

**Products marketed for “health purposes”**—may make claims that are allowable and similar to those for human dietary supplements, following structure/function guidance, absent nutritional references.

Examples:

“Supports normal healthy joint function”

“Helps maintain cardiovascular health”

“Supports normal liver function”

If claims guidance isn't followed, FDA can issue a warning letter and may also take further action if corrections aren't made.

### Important Changes

One may think since human dietary supplements weren't included (with some exceptions) in the Food Safety Modernization Act (FSMA) legislation, animal supplements would also be excluded. This is not the case. All animal supplements marketed as food (nutritionals) fall under FSMA rules.

Additionally, two specific areas significantly affected for human and animal products alike are the supply chain and customs. Raw materials and raw materials suppliers will be impacted, and scrutiny of materials by customs will increase. Companies should be aware of the effects of FSMA and each should diligently examine its entire supply chain to prepare.

One of NASC's primary objectives is to keep members ahead of the regulatory curve, using the Preferred Supplier Program to help both supplier members and brand partners. If you have questions, please come to the talk, "[Critical Industry Synergies Between Human & Animal Supplements](#)," on Friday, Oct. 7, from 2:30 to 3 p.m. at SupplySide West 2016 at SupplySide Central. 



*William Bookout is a founding member of the [National Animal Supplement Council \(NASC\)](#), serving as president from 2002 to May 2012, returning as president in February 2014, and continuing as chairman of the board of directors of the nonprofit organization. He was president of Genesis Ltd. before its acquisition by Kemin Industries, and served as vice president of global sales at Kemin before his role at NASC. Bookout has been selected by Health Canada to serve on the expert advisory committee for veterinary natural health products. He received his bachelor's degree from the University of Wyoming and a master's from Pepperdine University.*

### Selected Resources

- 1 [National Animal Supplement Council](#)
- 2 [Association of American Feed Control Officials \(AAFCO\)](#)
- 3 [FDA's Regulation of Pet Food](#)
- 4 [Food Safety Modernization Act](#)
- 5 [North American Compendiums, LRVNHP Program](#)
- 6 [Structure Function Claims, Small Entity Compliance Guide](#)