



JAVMAnews

January 15, 2017

Supplement companies made changes after facing crackdown

Feed control officials, FDA had planned enforcement event 15 years ago

By Katie Burns

Posted Jan. 4, 2017

The availability of glucosamine for animals seemed to be in question 15 years ago.

An Aug. 15, 2002, *JAVMA News* article, "[Facing crackdown, dietary supplement companies promise changes](#)," summarized the situation as follows: "In January, the Association of American Feed Control Officials unveiled a plan for helping states remove unapproved dietary supplements for animals from the market. For several years, products promising therapeutic and nutritional benefits unsubstantiated by the Food and Drug Administration were being sold in pet stores, in catalogs, and on the Internet in increasing numbers."



According to the article, AAFCO, in cooperation with the FDA, planned on targeting an unspecified ingredient. Many guessed that the ingredient would be glucosamine.

The article goes on to say that, in a letter to AAFCO, "The AVMA stressed the importance of glucosamine products for

treating osteoarthritis in companion animals, and encouraged AAFCO to defer to the discretion of state regulators in regard to this particular ingredient." The National Animal Supplement Council, a nonprofit coalition of companies founded in 2001, "quickly put together a program that it hopes will assuage AAFCO and the FDA's concerns."

The ongoing program, which applies to supplements for nonfood animals, involves standards for labeling and quality control and a system for reporting adverse events. Under the labeling standards, products cannot promise therapeutic or nutritional benefits but can claim to affect the body's structure or function—such as by claiming that glucosamine supports joint health.

The program seems to have assuaged regulators' concerns. AAFCO dropped its plan, and the FDA exercises enforcement discretion. Glucosamine and other supplements remain on the market for animals.

In 2002, the AVMA passed a policy supporting the availability of glucosamine. The AVMA rescinded the policy last year, however, partly because of a lack of data for the efficacy of glucosamine in management of osteoarthritis.

Feed control officials

The FDA doesn't recognize supplements for animals, just food and drugs. Ben Jones, associate director of the Office of the Texas State Chemist and a past president of AAFCO, said AAFCO "had several task forces that were put together over the years looking at these products and how they might be regulated and never really came up with a successful pathway."

AAFCO develops model state regulations for animal foods, although it has no enforcement authority. Jones said AAFCO, certain states, the FDA, and the NASC held discussions in 2002 to carve out a means for animal supplements to be marketed. Since then, many states as well as the FDA have applied enforcement discretion, and the same groups continue to meet.

Everyone agreed the parameters are that you can't make egregious drug claims. So you can't make statements about curing cancer, preventing arthritis."

*Ben Jones, past president,
Association of American Feed Control Officials*

The deliberations resulted in a framework under which companies must follow certain parameters to distribute supplements for animals without interruption. The products must be for nonfood animals—dogs, cats, and horses. The companies cannot make nutritional claims or references on the label or anywhere else.

"What they could do was talk about how this impacted the structure or function of the animal," such as by helping maintain a healthy skin and coat, Jones said. "In those deliberations, everyone agreed the parameters are that you can't make egregious drug claims. So you can't make statements about curing cancer, preventing arthritis."

In Texas, companies should register animal supplements with the Department of State Health Services. Also in Texas, if a company incorporates supplements into animal food, other than an approved ingredient such as a vitamin, the food is considered adulterated.

"Safety has always been a concern with these products," Jones said. There might be a history of safe use in humans, he said, "but that information is generally not available for animals, and then animal species may differ in their reaction to the different products."

When animal supplements really began to hit the marketplace in Texas 15 to 20 years ago, dealing with the products took up a lot of time and resources for the Office of the Texas State Chemist. Once a framework was developed for the products, most companies stopped making outrageous claims.

Still, Jones would prefer to see the products go through some sort of formal review and approval process for safety and efficacy.

Supplement companies

Bill Bookout, president of the National Animal Supplement Council, has a background as a business executive in human and veterinary medicine. In consultation with his veterinarian, he also gave supplements to his two Labrador Retrievers—joint supplements for the dog with hip dysplasia and multiple supplements for the dog with cancer.

He founded Genesis Ltd., which was acquired by Kemin Industries Inc. in 2012, to sell supplements exclusively to veterinarians. He said, “Supplements are not a magic bullet, but they can be a valuable component of a comprehensive care program. And personally, I believe that the veterinarian was the best person in position to coordinate all aspects of care.”

In April 2002, 26 companies had met in response to the AAFCO strategy to remove animal supplements from the market. Bookout said, “Our objective was to get the majority of the industry together to design and implement a program of self-regulation that was fair, reasonable, responsible, and consistent, with input from the regulatory agencies, both state and federal.”

Eighteen of those companies stayed with the NASC, which as of Dec. 5, 2016, represented 142 members—or about 90 percent of the industry by consumer spending, Bookout said. About half the companies sell equine supplements, and the other half sell supplements for dogs and cats.

Supplements are not a magic bullet, but they can be a valuable component of a comprehensive care program.”

*Bill Bookout, president,
National Animal Supplement Council*

To earn the NASC Quality Seal, members must follow standards for good manufacturing practices, participate in the NASC Adverse Event Reporting System, and follow labeling and claims guidelines. Companies that earn the NASC Quality Seal must pass an audit by the NASC every two years.

The NASC also tests members’ products randomly from the marketplace to see whether the ingredients meet the label claim. If an issue is identified, corrective action is required.

Why not pursue drug approvals for supplements? For most supplements, Bookout said, there is limited opportunity for the manufacturer to recoup the investment in research and the approval process because courts have held that natural substances cannot be patented.

Bookout said veterinarians can make a statement or speak at a meeting saying “they find a product or ingredient to be beneficial for contributing to curing, diagnosing, preventing, treating, or mitigating a disease process, but when a company uses that information, then that becomes problematic, and that crosses the line. So, is it ideal? No. Is it workable? Absolutely.”

The NASC did submit research for glucosamine and methylsulfonylmethane to be approved as feed ingredients. The FDA declined, saying the ingredients have no demonstrated nutritional purposes.

Bookout said the NASC is working with the FDA to come up with a more formalized policy on animal supplements.

FDA assessment, actions

In a 2016 statement to JAVMA News, the FDA noted that the Dietary Supplement and Health Education Act of 1994 created a new definition and regulatory framework for dietary supplements.

“However, the agency’s assessment of the law is that it was not intended (to) and does not apply to animal feed, including pet food,” according to the statement. The AVMA supports that position and does not believe the act should be modified to include animals.

According to the statement, “Thus, products marketed as dietary supplements or ‘feed supplements’ for animals remain subject to the same statutory standards as they were prior to DSHEA, i.e., they are considered ‘foods’ or ‘new animal

drugs' depending on the intended use."

The FDA has taken regulatory actions against animal supplements in certain situations. The agency noted in an Oct. 7, 2016, warning letter to Buck Mountain Herbs Botanicals Inc. that the company's website made statements such as that bugleweed is for mild hyperthyroid conditions. A Dec. 17, 2015, warning letter noted that Advantage Biosciences Inc. made statements online and on labeling such as that "Resveratrol can be used as a cancer therapy by itself or combined with other therapies."

In 2015, a court order prohibited sales of RenAvast in the United States, according to the JAVMA News article "Banned in one name, allowed under another" (see JAVMA, [Oct. 15, 2015](#)). According to the FDA complaint, manufacturer Bio Health Solutions LLC had claimed the product could treat or prevent kidney disease in cats and dogs.

Under the court order, the same product could be sold in the United States under a different name and with different marketing.

Related JAVMA content:

[Assessing pet supplements](#) (Jan. 15, 2017)

[Facing crackdown, dietary supplement companies promise changes](#) (Aug. 15, 2002)

Copyright © 2017 American Veterinary Medical Association