

Is Corta-Flx Mislabeled?

Its competitors think so. But this update from our May nutraceuticals field trial concludes otherwise and brings those competitors' own labels into question.

Over the past five years, horse owners whose animals have suffered soundness problems have become well used to the terms "glucosamine," "chondroitin sulfate," "perna mussel" and other compounds. These substances form an important defense against joint pain, athletic stresses and other debilitations. Indeed, these so-called "joint nutraceuticals" offer new hope to keep horses in productive work.

But our use of these substances is now being questioned and could one day be denied outright, largely due to the open verbal warfare that's breaking out in the industry. Confusion over labeling, public back biting, charge and countercharge are flourishing in this once-tranquil backwater of the equine industry.

Since our May field trial that reported on the effectiveness of 25 new joint nutraceuticals, we've learned that one of America's highest authorities on animal feeds, the American Association of Feed Control Officials (AAFCO), doesn't recognize the principal ingredients of the joint compounds with which we've become so familiar.

Neither the National Research Council (NRC) nor AAFCO--the sources the Food And Drug Administration (FDA) relies upon for defining animal nutrition requirements--nor any published research has established a "need" for such common joint-supplement ingredients in the equine diet. This failure to be "defined" by AAFCO or approved by the FDA means these substances are currently unapproved feed ingredients.

Horse Journal's May field trial may have been a flash point. Shortly after the release of our May 1999 article, we received a letter that stated several manufacturers' "regret and disappointment" with our findings on Corta-Flx, not because Corta-Flx didn't work, but because the product did not list a guaranteed analysis on its label (see letter in sidebar, p 4).

The letter claimed that our story is "legitimizing the idea that a manufacturer can ignore state and federal labeling requirements." The Corta-Flx label provided "a dietary formulation of water soluble Chondroitin Sulfate, Amino Acids, vitamin and minerals for horses" (see p 5). But Corta-Flx was forthcoming when we asked for, and published, an ingredients list that went beyond what Corta-Flx printed on its label.

In separate correspondence, representatives from Farnam and Vita-Flex also claimed that guaranteed analyses, including specific amounts, are "mandatory" on labels for protein (including amino acids) and certain vitamins and minerals.

Grand Meadows' Nick Hartog and Angela Schlinger, manufacturers of Horse Journal-recommended Grand Flex, stated their "most significant aspects of concern" were product registration; the "requirement that for a nutritional supplement, the names and levels of ingredients be included on the label"; and "levels of chondroitin sulfate and their effect."



We put a lot of money into our performance horses, and supplement manufacturers are well aware of it.

Grand Meadows claimed there was "no evidence, with the exception of South Carolina, that Corta-Flx is registered for sale with appropriate feed regulatory agencies."

In subsequent correspondence, these companies provided pages from the FDA/Center for Veterinary Medicine (CVM) Compliance Policy Guidelines (CPG) 7126.04 and the 1999 AAFCO Official Publication. In both instances, Farnam, Vita-Flex and Grand Meadows seem to be confusing the essential differences between regulations concerning pet food and those for horse feed.

Label Development

Investigating further, we've learned:

- The Corta-Flx label could not violate existing federal regulations

by not providing guaranteed levels of all ingredients because, for better or worse, there are no federal regulations governing guaranteed analysis on equine supplements. Official federal regulations only exist for medicated feeds fed to food-producing farm animals. The FDA does prohibit drug claims and requires all substances in animal food be "generally recognized as safe (GRAS)" or an approved feed additive.

However, the FDA/CVM publication CPG 7126.04, cited by Grand Meadows, is only a policy statement. In essence, it essentially outlines what the FDA might do if it ever had to rule on a question concerning a pet supplement. (AAFCO defines a pet as "any domesticated animal normally maintained in or near the household(s) of the owner(s)." For the purpose of feed regulations, horses are considered livestock.)

Also clear in that policy statement is that any ingredient in a pet-food supplement must be a nutrient recognized by the NRC as essential for the nutrition of the animal in question and be proven GRAS for that species. Chondroitin, glucosamine, glycosaminoglycans and perna mussel do not appear as essential nutrients in the NRC feeding guidelines for any animal, let alone a horse.

*The claim that the Corta-Flx label violates AAFCO model regulations is also impossible, since AAFCO cannot make regulations, only recommendations (see p 2 and June 1999 p 19). However, individual states often do adopt AAFCO guidelines in whole or in part as law.

*On top of that, the suggestions put forth by AAFCO refer to bags of grain and products to be mixed into feeds in bulk form, not to supplements being top dressed or dosed to individual animals. Even AAFCO is acutely aware that their existing recommendations can't be easily translated to many types of supplements. Plus, AAFCO's suggestions also contain exceptions to their recommendations, including one that states protein content is not required if the product is not intended as the animal's primary source of nutrients.

GRAS Is The Game

We asked representatives from Equine America, manufacturer of Corta-Flx, about their label and registration with specific states. They reported being registered with South Carolina, Michigan, Missouri, Montana, New Jersey, Wisconsin, Oregon and Florida with applications pending in more states.

When Horse Journal inquired about the Corta-Flx label, Equine America President Bruce Snipes's immediate reply was that the labels had been changed concurrent with our May report. When we asked Snipes why he changed the label, he replied he had heard rumors that his label would be challenged and he knew it required modification.

There Are Some Laws

1. Fact: It is against existing state and federal regulations to sell products containing ingredients that are not GRAS, not an approved feed additive or not defined by AAFCO. Neither the FDA nor AAFCO nor any individual state recognizes any of the following:

Chondroitin sulfate
Glucosamine
Perna mussel
Mixed glycosaminoglycans (also known as mixed mucopolysaccharides).

2. Fact: It is against federal law to make medical claims for a supplement. The FDA defines medical claims as statements that the ingredient(s) may prevent, treat, cure or mitigate a disease.

But Snipes thought the real vulnerabilities in his label centered around the ingredients list and health claims, not a supposed hidden ingredient as competitors claimed.

Equine America's new label has been approved by these states and contains in its list of ingredients only substances that have an existing AAFCO definition, have been granted GRAS status, and whose level is verifiable by a laboratory method recognized as accurate by AAFCO.

The FDA/CVM's current statement on supplements begins by saying there should be a "known need for each nutrient ingredient represented to be in the product for each animal for which the product is intended." Neither the NRC or AAFCO believes those needs exist for joint nutraceuticals. In addition, the AOAC--AAFCO's expert laboratory reference on these matters--does not have an approved testing method listed for these specific substances.

We asked Eli Miller, chairman of the feed-labeling committee of AAFCO, if ingredients such as MSM, chondroitin sulfate, creatine, glucosamine, glycosaminoglycans and perna mussel would be considered inappropriate for inclusion in an equine supplement. He replied, "Generally, it is my understanding that the ingredients above are not defined by AAFCO and are not FDA-approved for use in feed. Thus, they are not approved for use in

Letter Of Complaint

"As a result of Horse Journal's review of Joint Nutraceuticals in the May issue, we felt compelled to notify you of our regret and disappointment as to the article's findings on the Equine America product, Corta-Flx.

"The issue we are addressing is not the efficacy of one product over another, the issue is the disregard on the part of Equine America to provide a guaranteed analysis on the

commercial feed such as horse supplements."

To get the views of a state feed regulation agency, we contacted J.R. Crane, program supervisor, Office of Product and Industry Standards, Virginia Department of Agriculture and Consumer Services. Crane said, "FDA has stated that chondroitin sulfate and glucosamine are unapproved feed additives for animal feeds. They are also not the subject of an approved New Animal Drug Application for use as an animal remedy. In addition, both substances are often derived from beef products.

"As such, the label of a horse nutritional supplement containing chondroitin sulfate and/or glucosamine derived from beef products must contain the FDA-mandated caution statement, 'Do not feed to cattle or other ruminants.' Should the FDA/CVM decide to take action, all products containing these substances in their ingredients list could themselves be considered adulterated."

According to Julie Zimmerman, feed program administrator of the Colorado Department of Agriculture, Colorado is taking a middle-of-the-road policy for now. Although the ingredients are indeed unapproved, regulatory actions in Colorado have been "put on hold" pending the AAFCO's suggested course of action on this nutraceutical issue.

Horse Journal also confirmed with Stanley Buscombe, program supervisor, Agricultural Commodities and Regulatory Services, Division of Inspection Services, California Department of Food and Agriculture, that California has declared glucosamine, chondroitin sulfate and other nutraceutical ingredients as not approved for use in animal feed.

California licenses locations that manufacture animal supplements and seeks to ensure that labels are in compliance with California Commercial Feed and Law Regulations. Penalties begin with seizure of the product, said Buscombe.

Corta-Flx's new label lists only known GRAS ingredients. For example, instead of listing "chondroitin sulfate," the new label says "animal protein products," which fits existing policies. This addresses where Equine America thought its competitors would attack its label, not registration or a lack of a guaranteed analysis, and took steps to correct it.

product. We find this issue particularly frustrating in light of Dr. Kellon's editorial in the February issue of the Horse Journal. Dr. Kellon focused specifically on the question of manufacturers who do not provide adequate information as to the nature and levels of ingredients in a nutritional supplement. By endorsing Corta-Flx as the 'New Leader in Joint Nutraceuticals' Horse Journal is legitimizing the idea that a manufacturer can ignore state and federal labeling requirements.

"The Horse Journal has become the leading consumer advocacy publication in the equine industry and as such we believe you have a responsibility to recommend products that adhere to established rules and regulations for the manufacture, labeling and marketing of nutritional supplements. In this case we feel Horse Journal has clearly abandoned this responsibility. "

Equicare Products, a division of Farnam Companies
Pro-Formula Laboratories
Uckele Health & Nutrition
Grand Meadows Nutritional Products Inc.
United Vet Equine
Vita-Flex Nutrition

Corta-Flx Label Changes

<p>Old Label: Note use of the words chondroitin sulfate.</p>	
<p>New Label: Chondroitin sulfate has been replaced by "animal protein products."</p>	

CORTA-FLX™ Solution
TEST FREE INGREDIENTS!
A dietary formulation of water soluble Chondroitin Sulfate, Amino Acids, vitamins and minerals for horses.

FEEDING DIRECTIONS FOR HORSES: Feed with the animal's regular feed or give orally. **IMPORTANT:** For the first 5 consecutive days (loading period) feed double amounts. For an average 1100 lb. horse (500 kg) feed 1 oz. (30 ml) daily. Feed others according to body weight - less for smaller horses and ponies and more for larger breeds.

PREPPING FOR EVENT: Feed the initial daily loading dosage for 3 consecutive days prior to strenuous exercise or competition, continue feeding this level for 3 days after event then return to regular maintenance level.

**FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN**
Shake well before using. Protect from freezing. Store in cool dry place.

NATURE'S OWN, INC.
AIKEN, SC 29801
MADE & PRINTED in the U.S.A.
Product No. 511A

CORTA-FLX™ Solution
Guaranteed Analysis

Manganese (mg)..... 1,129ppm	Glutamine (mg)..... 1.0%
Copper (mg)..... 421ppm	Proline (mg)..... 6.37%
Sulfur (mg)..... 6,020	Glucosamine Acid (mg)..... 0.50%
Vitamin B16 (mg)..... 504 mcg/g	Glycine (mg)..... 1.0%
Ascorbic Acid (mg)..... 862 mg/g	Aspartic Acid (mg)..... 0.17%

Ingredient Statement
Water, Sugar, Animal Protein Products, L-Glutamine, Glycine, L-Lysine, DL-Methionine, L-Proline, L-Alanine, L-Arginine, Ascorbic Acid, Vitamin E Supplement, Ascorbic Acid, Manganese Sulfate, L-Serine, L-Methionine, DL-Phenylalanine, L-Histidine, L-Threonine, L-Tyrosine, Pyridoxine HCl, L-Ascorbic Acid, Copper Sulfate Sulfur, Kartman Gum, Sodium Borate (a preservative), Yucca Schottigera Extract (a natural flavoring agent), natural and artificial flavoring.

FEEDING DIRECTIONS
Feed 2 oz. (60 ml) daily for the first 5 consecutive days (loading period) with the horse's regular feed or give orally. Thereafter, feed 1 oz. (30 ml) daily.

**FOR ANIMAL USE ONLY • KEEP OUT OF REACH OF CHILDREN
STORE IN A COOL, DRY PLACE • PROTECT FROM FREEZING
SHAKE WELL BEFORE USING**

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which undergo rigorous drug testing. None of the challengers has yet to produce any test results that confirm the allegations of devil's claw or any other undisclosed substance either.

Bottom Line

As we sorted through this story, it became clear that the problem is not really the FDA or AAFCO but the manufacturers themselves. Shannon Jordre, commercial feed and animal remedy specialist, South Dakota Department of Agriculture, stated:

"The supplement manufacturers and marketers have not exactly made it easy for regulators to deal with these products. I don't think it would be that difficult to develop definitions for some of these ingredients, and some of this work is taking place behind the scenes.

"Some of the companies don't seem to be interested in cooperating with each other to do this work together, though, thus a common standard of identity might be difficult to establish for some of these products. Some of the manufacturers and marketers also want to continue making drug claims for these products, and are reluctant to work on definitions for that reason, as well."

Definitions and regulations are probably not far off. AAFCO's nutraceuticals subcommittee gave its board of directors final recommendations in June. Although no decision has been released, we're told it's likely manufacturers won't be allowed to use broad definitions to cover the actual ingredients.

For the consumer, the worrisome aspect of what's happened is not so much that a group of manufacturers decided to take aim at a competitor with a promising new product, but that compelling Equine America to change its label may have created a monster. The new Corta-Flx label may be "acceptable" in all states, but we believe it is virtually worthless to the consumer. How are we supposed to know that "animal protein products" is actually chondroitin sulfate?

What's next? Will the words "vitamin C" have to be replaced by "purified fresh-grass extract"? (Vitamin C isn't "approved" for horses either.) How will we know what's in these supplements? How will manufacturers disclose to us and to consumers exactly what these acceptable definitions mean? This is not a worst-case scenario of what could happen.

It's here.

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Uckele Joint & Bone

Max Flex Chondroitin contains 1,750 mg per oz. of 95+% chondroitin sulfate in an alfalfa meal base without any non-nutritional fillers. Chondroitin sulfates are found in the cartilage and connective tissues of animals, and are part of the family of glycosaminoglycans, which are produced naturally in the bodies of animals.

INGREDIENTS

Dehydrated Alfalfa Meal, Chondroitin Sulfate, Mineral Oil, Propionic Acid

Farnam Max Flex Chondroitin

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