
Animal Supplement Regulation

By Lisa Ross-Williams

Transcribed interview with Bill Bookout 2004

Welcome to another informational If Your Horse Could Talk show. I'm your host Lisa Ross-Williams and today we'll be covering the Animal Supplement Regulation issue which could impact your access to common dietary supplements for your companion animals. I'm discussing this issue with Bill Bookout, President of the National Animal Supplement Counsel.

Lisa-Welcome Bill. Thanks for being with us today and shedding some light on this serious and complex issue.

Bill-We appreciate the opportunity to talk to your listening audience. This certainly is an issue that is not only complicated, it's an issue that most people don't understand or even realize it exists.

Lisa-Before we jump into all the details, could you please briefly explain what is at state for companion animals and their owners?

Bill-To summarize and not to blow this out of proportion-What really is at stake is the continued availability of supplements that are similar to human dietary supplements for companion animals, primarily defined as dogs, cats, and horses.

Lisa-So these are supplements that could contain Glucosamine, Chondroitin, MSM, herbs and antioxidants. These are fantastic supplements that many animal owners are using for their companion animals.

Bill-Absolutely. Products that people commonly use and don't question the availability or continued availability of product like Glucosamine and other joint supplements are in danger of potentially being removed from the market.

Lisa-And these are the same type of supplements available for humans because of the DSHEA bill, which we will discuss in a second. What does Non-human food chain

animals mean? That is our dogs, cats, and horses, right?

Bill-Yes, animals not intended for human food consumption in the US.

Lisa-In 1994, Congress passed the DSHEA bill. Can you explain what this did?

Bill-Prior to 1994, dietary supplements for humans were caught in the same position as supplements for animals today. They were either considered a food or drug and they don't fit neatly into those two categories. Recognizing this was a deficiency and with the increased popularity and demand from consumers as well as the benefits recognized, Congress passed the Dietary Supplement Health Education Act in October 1994 which was signed by President Clinton. This created a category for dietary supplements for humans. Unfortunately at that time, Congress didn't consider that these products had become tremendously beneficial for companion animals. So specific language was not included in the Bill that recognized non-human food chain animals, therefore there is no category for animal supplements, although 1000s of products are available in the marketplace today.

Lisa-It's my understanding in 1996, the FDA determined this act didn't apply to our animals. What impact did this have and how did it get the ball rolling with this issue now?

Bill-Recognizing the benefits of these types of products for people, the animal industry began to increase in terms of popularity. People made the natural assumption that these types of products such as a joint product containing Glucosamine, Chondroitin or MSM would also be beneficial for animals so the animal supplement industry began to grow. The FDA came out in 1996 and in a district court opinion based on a reference to a cow, the FDA Center for Veterinary Medicine decided that the DSHEA legislation was not intended by Congress to apply to animals. Whether that is true or not is a matter of debate but the fact that animals were not specifically mentioned in the bill, the FDA relies on that opinion to hold the DSHEA does not apply to animals. However, it didn't stem the progress or consumer demand for these types of products, industry continues to develop them, people buy the product and realize the benefits with animals by helping to extend the quality or quantity of life for

their companion animals. Well, recognizing this was an issue, the two regulatory agencies (the State Department of Agriculture that oversees animal feed products and the Department of Agriculture nationally), decided there is no category for dietary supplements for animals. These agencies are given guidance by American Association of Feed Control, Officials (AAFCO). This is a non-regulatory body that provides guidance to various states Department of Agriculture to gain consistent regulatory environment for animal feed products. Even though AAFCO recommend consistent regulatory policy, states are at liberty to accept these recommendations or not to follow them.

Lisa-Lets talk about AAFCO. I want people to understand that they are just a private association, not a government agency. Correct?

Bill-Yes, AAFCO is a non-profit organization. However, most states, about half do follow the recommendations given. AAFCO does produce a valuable service for the State department of Agriculture to gain consistency in the market. Most people do not understand that AAFCO is not a regulatory body and has no regulatory authority.

Lisa-In 2001 from what I understand AAFCO recommended removing these animal dietary supplements from the market. Is that when your organization, National Animal Supplement Counsel was formed?

Bill-Yes. There were a couple attempts through AAFCO to try and come up with ways to deal with these types of products. NASC was formed in 2001 out of frustration with the lack of progress from other committees within AAFCO like Botanicals & Herbs and Novel Ingredients task force, to come up with a reasonable way to deal with these ingredients that were being included in animal supplements. These ingredients were unrecognized for purposes they were being used. In other words, they were unrecognized as feed ingredients or they were being utilized for a purpose other than the approved purpose. Here's an example I think most horse owners can relate to. Garlic is approved as a flavoring agent but it is not approved for other uses such as being an insect repellent. So if the quantity of garlic in a specific product were greater than that which feed control officials have determined as an appropriate level for flavoring, then this is an example of an ingredient that was in a

product greater than what would be for an approved purpose. More common ingredients like Glucosamine and Chondroitin in joint products are unapproved ingredient in animal feed as they are typically utilized for joint health benefits.

Lisa-Do herbs fall into this category?

Bill-Certainly. AFFCO formed a couple committees which were a cross-functional team consisting of representatives, FDA, State Department of Agriculture, and industry representative to come up with a way to deal with the increase in demand and the use of these ingredients. In 2001, the new president of AFFCO, John Breitsman came out with a hard line stand and said they would remove products that contained unapproved ingredients or approved ingredients utilized for unapproved purposes. It was commonly felt that Glucosamine and Chondroitin products would be the first to be removed.

Lisa-But these products are so important to our animals.

Bill-They are tremendously important and it's important for the listening audience, especially the regulatory people that the decision available to animal owners is they can make the decision to humanely euthanize their companion animals. However, the use of these products, especially joint product, we feel can help extend the quality and quantity of life for that animals.

Lisa-This doesn't make a whole lot of sense, especially since these products are available for humans. Let's talk about NASC. Why was it formed and where you trying to work within existing framework of the issue and so you came up with the Compliance Plus program. Please explain this.

Bill-NASC was formed prior to submitting The Compliance Plus program to regulatory agencies. NASC is a non-profit trade association by responsible industry participants who looked at the issue and said that with the lack of positive progress and acceptable outcome from the other committees, attempts that have been put forth to resolve this issue. It's not easy to resolve because the product are either considered animal feed or drugs. They don't neatly fall into either of those categories. What we

did on behalf of the industry is to look at what objections all the stakeholders had, what are the objections and concerns of the regulatory agencies and industry and what's in the best interested of the ultimate stakeholders which are the animals and their owners. We tried to cover the identified weaknesses using 20/20 hindsight in the DSHEA bill and introduced Compliance Plus which was founded on these premises. We would establish an adverse event reporting system on behalf of industry because regulatory people were concerned about the safety of the products. Although there are millions and millions of administrations given routinely, there was not consistent way to report adverse events so we could manage risk, identify ingredients and products that were problematic. We committed to develop consistent labeling throughout the states, however did not want to support the use of overt drug claims. These products are not magic bullets, they won't cure degenerative joint disease or cancer or other chronic degenerative disease in animals. However, they can be beneficial as a comprehensive component of care. We developed efficient labeling guidelines that give info to the consumer similar to those for human dietary supplements. We needed the ability to effectively communicate to the consumer without using overt drug claims. The FDA really doesn't know how many products or ingredients are in the marketplace, and we wanted to help get a handle on that so we formed a scientific advisory committee consisting of recognized experts from both within the industry as well as non industry to identify the total scope of products from our members, the ingredients in the marketplace and perform risk assessment, and recommend additional labeling procedures. We also chose to submit, if possible, ingredient definitions so we could get these ingredients approved as feed ingredients. We also said we'd develop consistent manufacturing guidelines so consumer and regulators could have a reasonable degree of faith in the processing of these products, similar to the Good Manufacturing Practice guidelines proposed in the human dietary supplement industry and required by drug manufactures. These were the four basic fundamental pillars of Compliance Plus. We really thought this was a responsible approach to address this issue given that there are 1000s of products and 100s of ingredients in the marketplace. It was a responsible approach that would meet the needs and concerns of all stakeholders.

Lisa-How was all this work NASC did welcomed by the FDA, AAFCO, and the other agencies involved?

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Bill-It was received tremendously well. We know that they are not used to receiving this level of cooperation from industry and we said from the beginning that an optimal outcome could only be achieved by considering the perspectives and requirements of all stakeholder and then coming up with a reasonable solution. We have received great encouragement and assistance by virtually everyone in the Center for Veterinary Medicine and and AAFCO.

Lisa-Let's talk about where we're at now. I understand that the FDA has now regulated the supplements as intended other than feed but as unapproved drugs of low regulatory priority. Explain what this means and why it's not a viable long-term solution?

Bill-We had three options. Initially when Compliance Plus was submitted, we offered to submit feed ingredient definitions, which are ultimately approved by FDA and AAFCO. We submitted definitions for Glucosamine and MSM, two very popular ingredients. The FDA Center for Veterinary Medicine reviewed the applications and denied approved as feed ingredients. Therefore, that pathway was closed. The only other option was the drug pathway. Most people know that to submit a drug application costs millions of dollars and years to approve. The limiting factors in the industry to have drug applications approved are the fact that the formulations can't be patented so there's no way for a company who goes through this process to recoup that. It is prohibitive for the animal industry to navigate this pathway due to extreme costs. After our meeting with the FDA in October of this year, these products are considered today, based on the intended use which is consistent with Federal Food, Drug, & Cosmetics act are unapproved drugs of low regulatory priority. However, they are not considered legal. These products are in an orphan category, neither feed nor drugs. Although they are still available in the market, the fact of the matter is they are illegal.

Lisa-It sounds like the whole system is bound by current law and everyone has their hands tied. But, there is something that can be done.

Bill-Exactly, It's important for the listeners to recognize that the regulatory people are

not bad people and have been tremendously encouraging as we have worked with them over the past 2 years. However, these people, no matter how much they agree with what we're doing, can't create or change the law. In our opinion, the only option for us now is to create new statutes and laws for a specific category for the supplements by introducing legislation in Congress.

Lisa-It sounds like that is the best bet. How does the process works and what needs to be done?

Bill-It takes time and money. We have met with elected officials in Washington DC; we spent a lot of time networking with elected officials, and those people who were ultimately involved in passing the DSHEA legislation as well as those who had some reservations about legislation. We need to introduce a bill in Congress and have a lobbying organization and other associates who are prepared to help us. Essentially a bill needs to be introduced in the next legislative session in Congress that specifically creates a category for these types of products. It's really the only way that is viable to address this issue effectively for all stakeholders, most importantly the animals themselves.

Lisa-Ok, the power is in the people. I try to tell people that once voice can be strong. So people who hear about this and say, "We don't want to lose the right to have these products for our animals. How can we get involved?"

Bill-We need to raise about \$300,000 in total to get legislation passed. It takes people who know the process and can gain access to the centers of influence who can assist in helping pass legislation. We are right now in the process of soliciting funds from industry, feed & tack stores and consumers to contribute to the cause. When people say, "I use these supplements, they are important for my animals; I'd be willing to sent \$20 to help support passing this legislation." If we split the \$300,000 up between the over 120 million people who this industry touches, it's not a lot. Once we have raised some money, have the bill drafted, we then can point to a specific number on that bill. Then consumers can get involved, contact their elected officials and tell them this issue is important. Right now, the elected officials don't even know this is an issue.

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Lisa-They don't realize a lot of important issues.

Bill-Consumer voices are heard and there are statistics that our elected officials keep track of. If they are contacted by a few people, they relate that to a number of votes and ultimately these officials answer to us; the voting public. They can contact their officials, let them know this issue is important and ask for their support on the specific bill. When we have that number, that's the time to get involved in a grassroots effort and get everyone involved.

Lisa-Any idea of the timeline?

Bill-We'd like to raise half of the \$300,000 by January, introduce legislation in the first quarter and get it resolved.

Lisa-How can people donate? Your website is www.nasc.cc. Can they donate through there?

Bill-Yes, we are set-up with a secure credit card processing system. NASC is a non-profit organization but we are not like a church so your donation is not tax deductible.

Lisa-For those who prefer to send a check?

Bill-Send that to NASC at PO Box 2568, Valley Center, CA 92082

Lisa-Bill, thanks so much for being with us today and I know the information you provided will get people thinking and hopefully involved. Please contact me when you have a bill number that people can refer to when contacting their representatives.

Bill-I want to leave your listeners with-Don't be complacent, step up and get involved.

Lisa-Your voice will be heard. Remember, the animals don't have a voice. We have to be that voice.

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