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Dr. Sharon Benz, Leader Nutrition & Labeling Team  
FDA – CVM  
Center for Veterinary Medicine  
7500 Standish Place, HFV-228  
Rockville, Maryland 20855

Dear Dr. Benz:

My colleagues and I are extremely concerned that removal of supplements designed and labeled for animals will endanger animal safety, for a number of reasons:

1. Removal of supplements labeled for animals will not solve the problem as long as human supplements regulated under DSHEA are still available. Since human supplements are not designed with the variation in animal size or unique physiologic needs in mind, this represents a significant danger to small animals. Owners have always bought and administered nutritional supplements for humans, and this practice will increase.
2. Removal of supplements labeled for animals will cut the legs out from under the growing efforts to generate data on these supplements. Most are not patentable, and we depend on ethical supplement companies to fund this research. If they cannot sell products recommended by veterinarians and used safely for years by pet owners, data will NEVER be forthcoming. Since the problem is lack of data, removal of supplements will not solve the problem.
3. Although this action is reportedly undertaken to assure the safety of companion animals I would simply ask, where are the significant numbers of adverse event reports? Why can't regulatory bodies, companies and veterinarians work together to generate data? AAFCO has systematically excluded input from stakeholders, especially. We believe that this action will meet with dramatic resistance. AAFCO and the FDA should utilize their limited resources more productively -they need to gather more information from those who have the most experience with these supplements, and help implement a new structure for optimizing patient outcomes and adverse event reporting.

Removal of animal supplements from sale will not solve the problem; indeed, it will significantly worsen the situation. Below are listed some possible solutions:

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1. Separate food animal and pet/exotic assessment criteria (even if supplements do represent food-chain issues, it is not reasonable to lump companion and zoo animals with food animals)
2. Create a separate category for regulation (such as the German Commission E or many others proposed in the literature)
3. Involve stakeholders (AAFCO has a very clear problem with involving veterinarians as advisors to the regulators!)
4. Utilize veterinarians as a first line of information gathering for toxicity data- implement existing prescription practices as a structure for outcomes and safety data.

Above all, avoid a New "Prohibition" - the public already owns herbs and to some extent nutraceuticals. There will be a public outcry if the FDA and AAFCO carry out this initiative.

Thank you for your time and attention.

Sincerely,

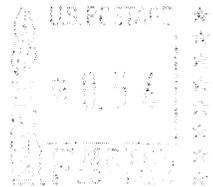
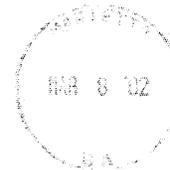


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Secretary/Treasurer, American Academy of Veterinary Nutrition  
Executive Director, Veterinary Botanical Medicine Association

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Kenneth Nobles, GA Dept of Agriculture  
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GA Senator Zell Miller  
GA Representative Johnny Isakson

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