



AMERICAN FEED INDUSTRY ASSOCIATION

December 5, 1997

Dockets Management Branch  
HFA-305, Room 1-23  
Food & Drug Administration  
12420 Parklawn Dr.  
Rockville, MD 20857

6468 '97 DEC -8 P1:26

Dear Sir/Madam:

Please file the enclosed letter from the Minor Species Animal Health Coalition dated December 5, 1997 in docket #97N-0217.

A copy has been sent to Dr. Stephen F. Sundlof, director of the Center for Veterinary Medicine.

Thank you for your cooperation.

Sincerely,

Richard Sellers  
Director, Feed Control and Nutrition

enclosure

97N-0217

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**MINOR SPECIES ANIMAL HEALTH COALITION**

December 5, 1997

Stephen F. Sundlof, D.V.M., Ph.D.  
Director (HVF-1)  
Center for Veterinary Medicine  
Food and Drug Administration  
7500 Standish Place  
Room 482  
Rockville, MD 20855

*Re: Concept Paper for Medicated Feed Use of Approved  
Animal Drugs in Unapproved Minor Species*

Dear Dr. Sundlof:

We are writing as a follow-up to our meeting last week with Dr. Steven Vaughn, Dr. George Graber, and other members of the CVM staff. The Coalition had requested the meeting to discuss its Concept Paper for Medicated Feed Use of Approved Animal Drugs in Unapproved Minor Species, submitted to you by letter dated September 8, 1997.

We appreciate that you could not participate in the meeting because of your required attendance at a last-minute meeting dealing with the agency's overall budget for the upcoming fiscal year. Nevertheless, we were disappointed that there were no senior CVM representatives who were familiar with the Coalition's Concept Paper that were available to meet with us. Our disappointment is heightened by the fact that three of the Coalition's representatives traveled from the Midwest specifically for the meeting, at considerable expense and time.

\* \* \*

The Coalition prepared its Concept Paper in a good faith attempt to address a troublesome problem to both animal agriculture and the agency -- the lack of FDA-approved drugs for minor species. The Coalition's decision to base its Concept Paper on a VFD approach stemmed from informal discussions with you, which suggested that this approach appeared to be viable.

Now it appears that the agency's attorneys are taking the position that the agency has no authority to adopt a VFD-based approach for the medicated feed use of approved animal drugs in unapproved minor species because medicated feeds are expressly outside

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the scope of the Animal Medicinal Drug Use Clarification Act. However, our legal counsel has advised us that AMDUCA can be interpreted so as to support the Coalition's VFD-based concept: While AMDUCA does not permit FDA to sanction any extra-label uses of drugs and medicated feed by regulation, it does not preclude the agency from concluding, as a matter of enforcement discretion, that certain uses of approved animal drugs in unapproved minor species pursuant to a VFD represent areas of low regulatory concern. Indeed, in the preamble to the AMDUCA final rule (61 Fed. Reg. 57,732, 57,739), FDA stated that it would address extra-label drug use outside the scope of AMDUCA -- such as extra-label drug use in medicated feed -- as a matter of enforcement discretion.

The use of the agency's enforcement discretion is precisely the approach taken in the Coalition's Concept Paper. This approach is no different than the agency's longstanding use of a Compliance Policy Guide to address the extra-label use of drugs in food animals before the passage of AMDUCA. If the agency's attorneys have concerns about the legality of the Coalition's suggested approach, we request that the matter be discussed by the agency's attorneys and our legal counsel at the earliest opportunity. Our counsel stands ready for those discussions at the agency's convenience.

\* \* \*

During the meeting, it was suggested by CVM representatives that, from the Center's perspective, the simplest approach would be if individual minor species producers wrote to the Center, and requested advice regarding whether specific medicated feed use practices in minor species are considered objectionable. The CVM representatives recommended that these letters be directed to Dr. Linda Tollefson.

The Coalition appreciates the suggestions that this letter approach may be the simplest approach from an administrative viewpoint. At the same time, the submission of numerous requests from individual producers would increase the overall burden on both industry and the agency. For that reason, our Concept Paper suggested a "global" approach of addressing the situation through a Compliance Policy Guide. We look forward to discussing with you and your staff in the near future how best to proceed, including but not limited to the submission of requests for advice from individual minor species producers. In the meantime, the Coalition will be working with a few individual producers that may be interested in submitting individual requests for advice.

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During the meeting, one CVM representative stated that the preponderance of comments on ways to encourage drug approvals for minor species and for minor uses (62 Fed. Reg. 33,781) supported extra-label drug use in feed. We believe it is important to clarify the position of this coalition, as well as that of The Coalition for Animal Health -- representing a broad spectrum of industries involved in animal agriculture. Both opposed extra-label use of drugs in feeds on a veterinary prescription basis. Importantly, that Coalition's comment supported use of the VFD mechanism. Moreover, the preamble to the AMDUCA final rule (61 Fed. Reg. at 57,739) stated that while a number of comments from individuals and minor species producer groups supported extra-label drug use in animal feed, comments from the American Feed Industry Association and the National Grain and Feed Association strongly opposed extra-label drug use in feed.

As stated in the Coalition's Concept Paper, the major reason for the feed industry's longstanding opposition to extra-label use of drugs in medicated feed was that mixing medicated feed pursuant to a veterinarian's prescription would have resulted in the medicated feed being regulated as a prescription drug under state pharmacy laws. With the passage of the Animal Drug Availability Act of 1996, drugs used in feed pursuant to a veterinarian's direction are VFD drugs; they are expressly not prescription articles under federal or state law. Thus, the primary reason for the feed industry's longstanding opposition to extra-label drug use in feed no longer exists today with respect to VFD drugs for minor species.

Another reason for the feed industry's longstanding opposition to extra-label drug use in feed was concern about human food safety and the potential for regulatory and financial liability in the event of unlawful drug residues. These concerns are lessened significantly if there is some FDA involvement in determining the drugs that can be used in unapproved minor species and the associated conditions of use, as contemplated by the Concept Paper.

\* \* \*

The Coalition's September 8, 1997 letter to you proposed holding a half-day symposium, at which Coalition members could present an overview of their industries and how the Coalition's VFD-based plan might be implemented. We continue to believe that a symposium would be an invaluable way to help educate CVM staff about the real world practices and concerns of minor species animal producers. We look forward to working with you and your staff to schedule and implement this symposium.

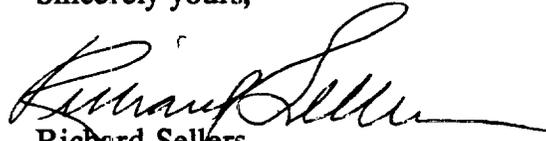
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In closing, the Coalition deserves a prompt response to its suggested concept. We are not wedded to our suggested concept, and welcome a constructive dialogue with you and your staff that would hopefully result in the best possible approach for making needed drugs available to animal agriculture, while not sacrificing the agency's legitimate concerns. The Coalition sincerely hopes that a workable approach can be developed so that alternative routes of reaching a solution will not be needed.

We continue looking forward to working with you and your staff to implement both short-term and long-term solutions for making animal drugs more available to minor species producers. We appreciate the Center's attention to this important matter.

Sincerely yours,



Richard Sellers

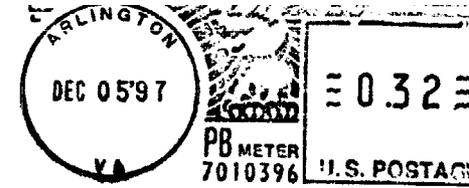
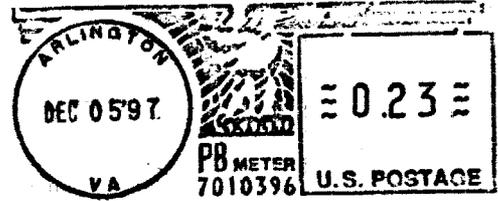
On behalf of the Minor Species Animal Health Coalition

cc: Dr. Linda R. Tollefson  
Dr. Steven D. Vaughn  
Dr. George Graber  
Dr. Meg Oeller  
Robert Guidos, Esq.



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