



AMERICAN FEED INDUSTRY ASSOCIATION

January 20, 1998

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Park Building, Rm. 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857

0594 91 JAN 20 10:29

Re: Docket No. 97N-0217 -- Minor Use/Minor Species Discussion Draft

Dear Food and Drug Administration:

These comments on CVM's December 19, 1997, Discussion Draft on Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses is submitted by the American Feed Industry Association. AFIA is the national, not-for-profit trade association representing manufacturers and distributors of animal feed, pet food, feed ingredients, and animal health products, and manufacturers of feed manufacturing equipment. Both individually and as a member of the Coalition on Animal Health and the Minor Species Animal Health Coalition, AFIA has had a longstanding interest in increasing the availability of approved animal drugs for minor species and minor uses.

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AFIA appreciates the agency's efforts to seek public input as part of developing its recommendations for legislative or regulatory changes to increase the availability of animal drugs for minor species and minor uses. The agency's June 1997, Federal Register announcement requesting comments and the opportunity for commenting on the December 19, 1997, Discussion Draft clearly go beyond FDA's legal obligations under the Animal Drug Availability Act of 1996 (ADAA) and are consistent with the spirit of cooperation between industry and government that led to enactment of ADAA.

AFIA understands the tight statutory deadline under which the agency is working. Nevertheless, AFIA does not believe that 30 days is sufficient time for the public to comment on the Discussion Draft. The Discussion Draft includes a number of far-reaching, open-ended ideas that will affect different minor species animal producer groups differently. Moreover, the expertise of these producer groups is generally not in the areas of drug regulation and related matters that are the focus of the Discussion Draft. For these reasons, significantly more than 30 days would be highly desirable.

In light of the short timeframe available for comment over the holiday season, AFIA was not able to address the Discussion Draft

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in its entirety. This letter only addresses several key points of particular importance to AFIA and its members.

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AFIA is deeply disappointed that the approach suggested by the Minor Species Animal Health Coalition in its "Concept Paper for Medicated Feed Use of Approved Animal Drugs in Unapproved Minor Species," submitted to the agency with that Coalition's September 8, 1997, letter to Dr. Sundlof (Attachment A), received absolutely no mention in the Discussion Draft.

In that Concept Paper, the Minor Species Animal Health Coalition suggested that FDA address, by means of a Compliance Policy Guide (CPG), the use of approved animal drugs in species for which the drugs are not approved. To get the benefit of FDA's enforcement discretion (to not take regulatory action) under the CPG, drug usage would have to be pursuant to a valid VFD, issued in the context of a valid veterinarian-client-patient relationship. The conditions of use set forth in the CPG would have to be followed. The CPG could be crafted in a fashion similar to the former "extra-label use" CPG.

As explained in the Minor Species Animal Health Coalition's December 5, 1997, letter to Dr. Sundlof (Attachment B), the Animal Medicinal Drug Use Clarification Act (AMDUCA) is not a legal impediment to the Coalition's suggested scheme. While AMDUCA does not permit FDA to sanction any extra-label uses of drugs in 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. 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. That is precisely what the Coalition's VFD-CPG scheme would do.

AFIA is mindful that some agency representatives and others have opined that VFD is a new, third class of new animal drugs (in addition to prescription and OTC); therefore, it is inappropriate to apply a VFD-based scheme to drugs that were not approved in the first instance as VFD drugs. AFIA thinks that contention misses the point. Without question, "prescription" drugs are a class of animal drug. Yet, under AMDUCA, an OTC drug (clearly a different class of drug than a "prescription" drug) can be used in an extra-label manner pursuant to the "lawful written or oral order of a licensed veterinarian," Section 512(a)(4)(A)(i) of the FDC Act. That veterinarian's order is commonly referred to as a

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"prescription." Similarly, with VFD, the term "VFD" refers to both a class of drugs for NADA approval purposes and the document issued by a veterinarian setting forth the conditions of drug usage. There is nothing inconsistent with having a veterinarian direct the use of an OTC feed drug for minor species, using a document called a "VFD."

We appreciate (as explained to the Minor Species Animal Health Coalition informally by CVM representatives) that agency attorneys may have concerns about the legality of the proposed VFD-CPG approach. However, we do not believe that those concerns are a sufficient basis for excluding the Coalition's suggested scheme from the Discussion Draft in its entirety. Rather, the suggested plan should have been included as one of the alternatives on which the agency is seeking public input, along with a discussion about the agency's concerns about legal authority and the Coalition's views on that issue. If that approach had been taken, it is possible that comments submitted to the agency may provide a better answer to the legal authority question. Moreover, the VFD-CPG plan could have served as a springboard for discussion, leading to the suggestion of other alternatives. Unfortunately, none of this happened.

The agency's decision not to address the VFD-CPG scheme at all is particularly disappointing in light of the fact that the Discussion Draft discusses other suggestions that FDA concluded were unlikely to be of significant help (e.g., improved supplemental application policy pursuant to Section 403 of the Food and Drug Modernization Act of 1997).

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As noted, AFIA believes that FDA can, under existing law, establish a VFD-CPG scheme for the use of approved animal drugs in unapproved minor species. If, however, the agency continues to believe that this approach is foreclosed by AMDUCA, AFIA suggests that the VFD provisions in Section 504 of the FDC Act be amended to confer FDA with the discretion to adopt regulations that sanction the type of relief sought.

AFIA envisions an amendment to Section 504 could take the same general approach as AMDUCA. Specifically, the amendment would authorize FDA to adopt the regulations setting forth circumstances when the use of an approved new animal drug in an unapproved minor species in feed would not be deemed "unsafe" and therefore violative. In parallel with AMDUCA, the drug use in feed would have to be directed by a licensed veterinarian within the context of a veterinarian-client-patient relationship, pursuant to a lawful veterinary feed directive. As with AMDUCA, FDA could, where

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appropriate, prohibit the use of specific drugs, establish safe residue levels, and require the development of an analytical method for detecting residues.

If the agency believes that a statutory amendment of the FDC act is necessary to implement a VFD-based scheme, AFIA would be pleased to work with the agency to develop suitable language.

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AFIA is pleased that the Discussion Draft recognizes, in a background section title, that "Extra-label Use Is Not The Answer." Page 8. (Page numbers are to the Web site version.) Thus, AFIA was surprised that one of the alternatives discussed in the Discussion Draft is amendment of the FDC Act to remove the prohibition on extra-label use of medicated feeds to allow such use in minor species. According to the Discussion Draft, "[t]his would allow medicated feeds to be considered as a dosage form product, similar to products such as injectable medications or orally administered tablets." Page 15.

AFIA is surprised that the Discussion Draft did not mention, let alone discuss, the feed industry's longstanding opposition to extra-label drug use in medicated feed. As is well-known to the agency, extra-label drug use in medicated feed pursuant to a veterinarian's direction could trigger the application of state pharmacy laws and requirements, thereby requiring that feed mills comply with requirements for a retail pharmacy and be supervised by a registered pharmacist. It was precisely these concerns, coupled with the Center's desire that a veterinarian be involved in the decision to use certain new therapeutic drugs administered in feed, that led to the ADAA's addition of new Section 504, regarding VFD drugs and feeds, to the FDC Act. Section 504 solved the state pharmacy law quagmire by deeming all VFD drugs and feeds to be not "prescription" articles under federal or state law. It appears that the alternative in the Discussion Draft would undo all of this by deeming medicated feeds for minor uses and minor species to be dosage form products.

AFIA's underlying concern is not that the authors of the Discussion Draft may not agree with AFIA's reasoning. Rather, AFIA's concern is that its viewpoint -- which is well-known to the agency -- was totally ignored in the Discussion Draft.

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AFIA is firmly convinced that the principal impediment to additional approvals for minor species and minor uses is increases in liability exposure to drug sponsors, particularly when coupled

with the lack of financial incentives to drug sponsors to add minor species and minor uses claims to their labeling. For example, it is AFIA's understanding (based on informal discussions with CVM officials) that, on a number of occasions, the sponsors of important approved new animal drugs with significant market shares have informed the agency that they would not add minor species/minor use claims to their labeling, even if data to support the supplemental approvals were to be made available to the company at no cost through the NRSP-7 or IR-4 Programs. That being the case, it seems unlikely that a number of the alternatives listed in the Discussion Draft, such as additional research funds for minor species/minor uses, a minor use database, or tax credits to help finance research, would overcome the basic drug industry concerns about increased liability. Similarly, it also appears unlikely that greater exclusivity protection against generic competition is the answer.

Although the Discussion Draft includes an entire section entitled "Incentives To Pursue Minor Use Drug Approvals," AFIA believes that this section misses the point, as it does not address the liability concerns at all. In fact, liability is mentioned only in passing in the section on "Data Sharing By Major Species NADA Holders": "In addition, if liability was a valid concern, it too would have to be addressed." Page 24. AFIA's informal discussions with CVM representatives appear to leave no doubt that liability is the major concern of major animal drug sponsors, and that this concern is well-known to CVM.

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One of the suggested alternatives is to amend the FDC Act "to permit the removal of a minor use animal drug from the market on the sole basis that it lacks FDA approval for the purposes for which it is labeled or promoted." Page 18. This suggestion makes no sense. It would make it easier for the government to remove an unapproved drug for use in minor species or minor uses than to remove any other unapproved drug from the market. If anything, given the dearth of approved products for minor species and minor uses, it should be more difficult to remove a product promoted for minor species or minor use from the market. Moreover, this suggestion overlooks the 60-year statutory history behind "new drugs" for human use and "new animal drugs," that a manufacturer can decide for itself in the first instance, subject to the risk of enforcement action if FDA disagrees, whether its product is a "new drug" or "new animal drug" that requires FDA premarket approval. That framework should not be disturbed.

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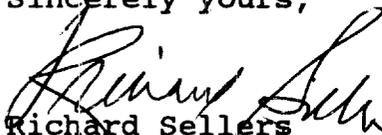
Two alternatives, conditional drug approval and alternate approval standards/expert review panels, are discussed only in connection with non-food animals. In connection with conditional drug approvals, the Discussion Draft explains that data used for the evaluation of human food safety must be complete for purposes of a drug approval; thus, a conditional approval based on incomplete data is not considered to be acceptable for a food animal drug. Although no rationale was presented for limiting the alternate approval standards/expert review panels alternative to non-food animals, AFIA assumes that the agency was also motivated by human food safety concerns.

AFIA has long believed that human food safety is, without question, the paramount consideration in FDA's regulation of animal drugs and feeds. We are pleased that the agency takes its responsibilities in this area seriously. At the same time, a conditional approval based on incomplete data or an approval based on alternate standards or expert review panels for a drug for minor species food animal use would in all likelihood represent a significant public health advance, when compared with compounds or drug uses that have not been reviewed by FDA at all. AFIA urges the agency to consider this trade-off carefully, rather than reject alternative approval mechanisms out of hand for all food animal minor species.

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AFIA appreciates this opportunity to comment.

Sincerely yours,



Richard Sellers  
Director of Feed Control and Nutrition

Attachments

**MINOR SPECIES ANIMAL HEALTH COALITION**

September 8, 1997

Dr. Stephen F. Sundlof, Director  
Center for Veterinary Medicine  
Food & Drug Administration (HFV-1)  
7500 Standish Place  
Rockville, MD 20855

**Docket 97N-0217  
Request for Comments on Development of Options to Encourage  
Animal Drug Approvals for Minor Species  
and for Minor Uses**

Dear Dr. Sundlof:

The undersigned organizations are part of the Minor Species Animal Health Coalition whose mission is to develop and help implement transitional and long-term solutions to allow the safe use of animal drugs in feed for minor species in a manner acceptable to both industry and CVM. The Coalition is pleased to submit the attached "concept paper" which provides for increasing animal drugs to minor species via the recently-approved Veterinary Feed Directive (VFD). This letter and concept paper have also been filed with the FDA Dockets Management Branch as the comments for the Coalition. Individual organizations may also make separate comments on behalf of their respective organizations.

The Coalition believes the VFD approach offers the best opportunity to safely provide animal drugs in feeds to minor species and maintain public and animal health. This approach follows CVM's stated goal of delivering more and safer drugs to animal producers. As provided for in the VFD program, the oversight by the veterinary medical profession would add another layer of protection in the safe delivery of animal drugs to producers. The attached plan allows only for use of therapeutic and prophylactic animal drugs sanctioned by CVM in a VFD manner for minor species only.

After reviewing the concept paper, we hope to schedule a meeting with you and your staff with several representatives of the Coalition to review the ideas presented here and answer any questions. At a later date, the Coalition would appreciate the opportunity to hold a half-day symposium with Coalition members presenting an overview of their industries and how the plan might be implemented. An updated concept presentation could be made at that time as well.

Thank you for your continued interest in securing additional, safe animal drugs for minor species production.

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If you have any questions, please contact the Coalition coordinator, Richard Sellers at the American Feed Industry Association offices (703/524-0810).

Sincerely,

American Feed Industry Association  
American Ostrich Association  
American Veterinary Medical Association  
American Sheep Industry Association  
National Aquaculture Association  
North American Gamebird Association

cc: FDA Docket 97N-0217

Under long-standing provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), it reduces the likelihood of litigation based on malpractice and product liability theories, respectively.

Under long-standing provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), any use of an FDA-approved new animal drug, including a drug used in medicated feed, in a manner inconsistent with its FDA-approved labeling was unlawful.

FDA has a long history of addressing, as a matter of enforcement discretion, the use in food animals of animal drugs in a manner inconsistent with their FDA-approved labeling. FDA adopted its first Compliance Policy Guide (CPG) on "extra-label use" of animal drugs in 1984. In addition to establishing the agency's highest priorities for regulatory attention (e.g., certain listed drugs of particular human food safety concern), the CPG set forth the general conditions under which the use of an animal drug in a manner inconsistent with its approved labeling would not ordinarily be the subject of regulatory action, including the following:

- o The drug use decision is made by an attending veterinarian within the context of a valid veterinarian-client-patient relationship;

- o There is no approved drug for the species and intended use in question;
- o The identity of the treated animals is maintained;
- o Extended withdrawal periods are assigned and followed to prevent illegal drug residues; and
- o The drug bears labeling information which is adequate to assure safe and proper use.

With enactment of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), Congress authorized FDA to establish, by regulation, the conditions for the lawful use of animal drugs in a manner inconsistent with their FDA-approved labeling. FDA's implementing regulations have, for the most part, codified the provisions of the "extra-label use" CPG.

Drugs used in medicated feed, however, are expressly beyond the scope of AMDUCA. Therefore, the use of approved animal drugs in medicated feed for unapproved minor species should be addressed by FDA by means of a CPG, much as FDA addressed "extra-label use" in a CPG before the enactment of AMDUCA.

One federal court dismissed a challenge to the "extra-label use" CPG by veterinarians on the bases that there were no issues appropriate for judicial review, and that the plaintiffs could only raise general grievances that were most appropriately addressed by Congress. Cowdin v. Young, 681 F.Supp. 366 (W.D. La. 1987). The Cowdin court's reasoning should be equally applicable if a new CPG addressing the use of approved medicated feed drugs in unapproved minor species should be challenged.

The "extra-label use" CPG stated that the "extra-label use" of drugs in medicated feed was an enforcement priority. This position, as well as the fact that AMDUCA excluded medicated feed drugs, stemmed from the feed industry's longstanding view that mixing medicated feed pursuant to a veterinarian's "prescription" would have resulted in medicated feed being regulated as a "prescription" drug under state pharmacy laws. These pharmacy requirements, which were intended for dosage form drug products and not medicated feed, would have represented a major disruption of existing production and marketplace practices for feed producers and distributors.

For example, feed mills would have had to employ a registered pharmacist to oversee all feed mixing operations; they also would have had to comply with retail pharmacy requirements (e.g., pharmacy counter).

The Animal Drug Availability Act of 1996 (ADAA) created the "veterinary feed directive" (VFD) category of animal drugs to provide an alternative to "prescription" status for certain medicated feed drugs. Like a "prescription" drug, a VFD drug can only be used when called for by a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. Importantly, however, by federal law a VFD drug or feed is not a "prescription" article under state law. Thus, state pharmacy requirements have no applicability to VFD drugs and feeds, and

the practical problems associated with "prescription" medicated feeds do not exist with VFD drugs and feeds.

The availability of the VFD mechanism presents an opportunity for FDA and industry to address the need for medicated feed drugs for minor species.

Another reason for the feed industry's long-standing opposition to "extra-label" drug use in medicated feed was concern about human food safety and the potential for regulatory and financial liability in the event of unlawful drug residues in food of animal origin. These concerns are lessened significantly if there is some FDA involvement – even on an informal level that falls short of the procedure used to approve animal drugs – in determining the drugs that can be used in unapproved minor species and the associated conditions of use (e.g., use levels, withdrawal times).

#### B. SCENARIO FOR USE OF APPROVED ANIMAL DRUGS IN UNAPPROVED MINOR SPECIES

By CPG, FDA would state that, as a matter of enforcement discretion, the use of certain specific approved therapeutic and prophylactic animal drugs administered in medicated feed for unapproved minor species is not a matter of regulatory concern. In contrast with the prior CPG (which only listed a few drugs that were regarded as enforcement priorities), the CPG would list specific drugs, minor species uses, use levels, withdrawal times, and other relevant details that ordinarily would not be of regulatory concern.

CVM's decision to list specific drugs and conditions of use in the CPG would be based on its review of one or more of the following:

- o Drug monographs prepared by the U.S. Pharmacopoeial Convention.
- o Extrapolation of drug approval data (e.g., from chickens to pheasants).
- o Published literature.
- o Unpublished data and information submitted to CVM by producer organizations, veterinarian associations, drug sponsors, academicians, or others.

The type and extent of data and information needed to support CVM recognition of a minor species drug use should be realistic. If the standard for CVM recognition is too stringent, the VFD-CPG concept will be of no practical utility.

To get the benefit of FDA's enforcement discretion (to not take regulatory action) under the CPG, drug usage would have to be pursuant to a valid VFD, issued in the context of a valid veterinarian-client-patient relationship. The conditions of use set forth in the CPG would have to

be followed. Relevant provisions of FDA's VFD implementing regulations, when adopted, would be applicable (e.g., recordkeeping and inspection, one-time distributor notification, written acknowledgment of distribution limitations).

The CPG could be crafted in a fashion similar to the "extra-label use" CPG. Use of the VFD process would establish procedures and safeguards comparable to the general conditions for "extra-label use" set forth in the former CPG.

The ADAA requires FDA to announce, by April 1998, its legislative and regulatory proposals for facilitating minor species approvals. Hopefully, within a few years, these reforms will make it economically feasible for drug sponsors to seek minor species approvals. The minor species CPG discussed in this Concept Paper is needed to fill an urgent current need. At the same time, the CPG should not remove incentives for drug sponsors to seek approvals for minor species after FDA's reform measures go into effect. To address both concerns, the CPG could be viewed as an interim measure and include a general "sunset" provision. It could also provide that, after the general "sunset" date and absent extenuating circumstances, no newly developed drug and minor species use would be listed in the CPG for longer than a specified number of years. This approach assumes that the sponsor of a newly developed animal drug is unlikely to pursue a minor species approval until after the drug has been approved and marketed for a major species.

**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.

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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.

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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.

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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.

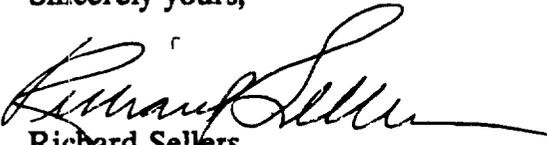
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In closing, the Coalition deserves a prompt response to its suggested concept. We are not wedded to our suggested concept, and welcome a constructive dialogue with you and your staff that would hopefully result in the best possible approach for making 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.