



AMERICAN FARM BUREAU FEDERATION®

225 TOUHY AVENUE • PARK RIDGE • ILLINOIS • 60068 • (847) 685-8600 • FAX (847) 685-8896
600 MARYLAND AVENUE S.W. • SUITE 800 • WASHINGTON, D.C. • 20024 • (202) 484-3600 • FAX (202) 484-3604

Internet: <http://www.fb.com/>

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January 23, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1-23, Park Building
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket No. 97N-0217 (Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses - (Discussion Draft))

Dear Sirs:

The American Farm Bureau Federation (AFBF) is the nation's largest general farm organization. As such, we represent a large portion of the producers who will be impacted by the actions proposed in this draft. Through the Coalition for Animal Health, AFBF has been an active participant in the negotiation leading to enactment of the Animal Drug Availability Act of 1996 (ADAA). We have provided comments on the proposed draft as a member of the coalition, but would like to provide some additional input from our organization.

General Observations

We do appreciate the commitment shown by the agency to improving the availability of animal drugs for all species and uses. The discussion draft demonstrates the agency's desire to make more animal health products available for minor species and minor uses. We commend the agency for this effort, but would like to offer some additional suggestions relative to it.

In general we note that a significant portion of the action in the draft is predicated on legislative action. We find this of concern due to the difficulty of moving legislation through the system in a timely manner. It was our understanding that the agency had an overall strategy to improve animal drug availability that would allow the plan to move forward with minimal additional legislative authority. We strongly encourage the greatest use possible of internal initiatives to expedite the process of increasing access to needed products by producers. We will continue to work with you by providing input to this process. We realize that some additional legislative authority may be needed, but we urge that this be kept to a minimum. We also recognize needs for additional research in some areas. We will work with you toward this end, but would also encourage you to make such needs known to the Animal Agriculture Coalition and through the Food Animal Integrated Research (FAIR) 2002 process.

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The proposed draft included a number of questions on specific issues. The following are responses to several of them:

Modification of Extra-Label Provisions

We agree with the agency that expanded extra-label use alone is not the answer to increasing the availability of and access to animal health products for minor species and minor uses. It may be helpful in some cases, but other actions are needed. As noted in the draft, regulations implementing the Animal Medicinal Drug Use Clarification Act (AMDUCA) had the unintended consequence of excluding the aquaculture and gamebird industries from access to legal extralabel use. This must be changed. Since the primary route of administration for these species is through medicated feed, we would encourage looking at modifying the Veterinary Feed Directive (VFD) as a way to provide access to products for these species. It may well be an appropriate route for other species as well.

Removal of Disincentives

We do agree that enforcement of existing regulations can serve to remove some disincentives; however, it appears that it is possible to make greater use of existing tools to facilitate this. Coordination with the Seafood, and Meat and Poultry inspection systems, to identify illegal drug use, would appear to be a cost effective way to identify problems and enhance enforcement. We recognize that this will not work in all cases, but it appears that it could be a cost effective tool to enhance this effort. We would encourage the agency to take care when enforcement is appropriate, to target distributors rather than focusing on producers. This is the best way to get at the probable root of such problems. We certainly agree that action should be taken to assure prospective supplemental NADA sponsors for minor use drugs that their parent application will not be put in jeopardy by the submission of a minor use supplement.

Enhancement of Existing Programs for Data Development

We can support the initiatives that are identified in this area; however, we would encourage expanding the NRSP-7 program to address needs rather than developing new programs as suggested in subheading 2 of this section of the draft. We would also note that the Sea Grant program is not mentioned. It would appear that this may be another potential source of funding for work with products for aquaculture. Subsection 3 of the draft includes a reference to university animal science departments. This should be expanded to include animal, avian and poultry science departments. Relative to expanded funding for research, we would again encourage the agency to be a part of the FAIR 2002 process that will help to define overall national animal research priorities.

Incentives to Pursue Minor Use Drug Approvals

We can in general support the initiative suggested. Producers do have concerns over the cost implications to their operations of extended exclusivity for products, but if no products are available without such incentive, this is a moot point. We most strongly support the negotiation of a shorter time frame for the review process.

Data Sharing by Major Species NADA Holders

We would support data sharing, but note that this should not be limited to only major species. Data from other minor species would also be appropriate for sharing. A question was raised relative to potential liability. It would appear that this could be addressed through language in documents authorizing the release of the data. Proper legal guidance is needed here.

Creation by Statute of a "Minor Use Animal Drug" Program

It is our understanding that these types of provisions were suggested early in the process of drafting the ADAA, but were removed at the request of the agency. It is unclear why the change of heart has occurred, but we would still support such action. If the Center for Veterinary Medicine (CVM) has not yet established a minor use/minor species work unit, it would seem prudent to do so as soon as possible.

Conditional Drug Approval for Minor Uses Involving Non-Food Animals

Conditional approval can be problematic, but it does appear that the constraints provide adequate consumer protection. Such a program could help lead to a more streamlined approval process. While it may be wise to first try this process with non-food animals, we would also support extending it to food animals as quickly as possible.

Alternate Approval Standard/Expert Review Panel for Minor Uses Involving Non-Food Animals

We could support the concepts outlined in the draft. It is almost certain that animal caretakers would find such products acceptable, especially in light of the limited number of alternatives currently available. In some industries the needed funding and expertise may be available to assist with this, but this is not universally true. We would encourage evaluation of this process for use with food producing animals as well. Again, initial use with non-food animals could provide a good test of the system.

International Harmonization

We strongly encourage international harmonization of standards. It is likely that non-government input could help in this process. In certain minor species/minor uses there appear to be adequate numbers of products approved to establish the program suggested. The proposal suggests ensuring that minor uses are included in harmonization. We strongly support this effort.

We appreciate the opportunity to provide these comments on the Discussion Draft. Once again we do appreciate CVM's commitment to improving the availability of minor species/minor use drugs. We look forward to continuing to work with the agency in the overall implementation of the ADAA.

Sincerely,



Richard W. Newpher
Executive Director
Washington Office