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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Subject: Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Use (Docket No. 97N-0217)

Dear Sir/Madam:

The American Farm Bureau Federation (AFBF) is the nation's largest general farm organization with member organizations in all 50 states plus Puerto Rico. Farm Bureau farm and ranch members produce virtually every agricultural commodity that is raised commercially in the United States, including fish, fish eggs and other "minor species."

AFBF welcomes the opportunity to provide comments on this subject, for the process that is ultimately developed will affect the care that our members can provide the animals they raise and has economic importance for their operations. We commend the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) on the timely publication and the leadership that they have provided in efforts to improve the process by which animal drugs are approved. We look forward to continuing to work with you in this process.

Access to safe and effective drugs is a necessity for producers of all livestock species, including those classified by the FDA as "minor species." Lack of approved drugs increases production costs. A costly drug approval process that cannot be distributed across a high volume of products creates economic barriers to the pharmaceutical companies to develop new drugs. Increased costs interfere with competition for markets serviced by producers in other countries.

We recognize and support FDA's efforts to assure consumers of the safety of their food supply as they also seek to provide access to animal drug products needed to protect the health and well-being of minor species animals. While this may present challenges, we do not see these as incompatible objectives.

In working with our members who are producers on "minor species" livestock, we have identified the following underlying concerns with the current situation:

- ▶ The limited number of animal health and therapeutic products that are currently approved for use by producers and veterinarians.

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- ▶ Access to and encouragement for the development of new products.
 - Finding ways to share data needed for the approval of new products.
 - Incentives to encourage development of new products.
 - Encouragement of outside organizations to sponsor/fund approval efforts.
- ▶ Recognition and use of species similarities in defining and approving drug use.
- ▶ Recognition of the differences associated with drug use at specific points in the life cycle when evaluating and labeling products.

We will expand on these concerns in our responses to several of the questions raised in the request for comments.

As the agency works to develop new rules, they must be both risk and science based. We strongly encourage the consideration of factors such as the likelihood of consumption (per capita consumption) and life cycle (direct consumption v.s. broodstock and other non-food production stages and uses) in development of these rules. They must also be comprehensive, giving simultaneous consideration of food safety, environment and economic issues.

A. Scope

The agency seeks comments on the criteria found at Sec. 514.1(d)(1) for the determination of a minor species or a minor use.

For those species produced for human consumption, the “per capita consumption” considerations suggested by the National Aquaculture Association and the American Sheep Industry Association add the component of risk assessment to food safety considerations. This should be considered when establishing human safety data requirements and should be a factor in defining those animals that are part of a “minor species.”

In considering the determination of major and minor species, as well as minor uses, FDA must keep in mind the potential risks to food safety from losing these industries to foreign competitors. In many cases, imported livestock, poultry, fish and shellfish have access to drugs and therapeutics, which are not available to U.S. producers and are undetectable at slaughter. These foreign grown food products place U.S. producers at an economic disadvantage. FDA must balance the human health risk of having limited oversight of imported food sources with the requirements placed on products used for domestically produced food products.

The current major/minor species determinations do reflect the species which are at an economic disadvantage at producing research data to support livestock and human safety and effectiveness. The major species have the economic incentives in place to drive extensive research. The minor species do not have the economics to drive extensive research. For this reason it is important to implement streamlined methods of approval, that still provide the same degree of human health protection associated with products approved for use in major species.

B. Creating Additional Statutory Authority

Should there be different standards for target animal safety and effectiveness of new animal drugs intended for use in minor species or for minor uses? Should there be different standards for human food safety for new animal drugs intended for minor species and for minor uses? If so, what should those standards be? Should the standards be the same for all minor species or uses? Why?

The primary reason to have multiple standards is to facilitate the approval of new products for species or uses where the data needed for approval is difficult to gather. If this is done, neither target animal nor human safety should be compromised. It makes inherent sense that non-food species, as well as non-food life stages (which do not enter the human food system), be evaluated on standards different than for species and life stages consumed by humans.

In addressing human food safety relative to aquaculture, we support the concept and definition of non-food fish for all early life stages (gametes, eggs, fry, fingerlings) as well as broodstock. We encourage CVM to work with the public and private aquaculture industry needs to define the size of fingerlings for each species so that they can incorporate this life stage into the definition. Early stage, non-food fish, which meet appropriate withdrawal considerations in later life stages, should be allowed to enter the human food supply.

We believe that the Veterinary Feed Directive program would provide a useful method of delivering drugs for minor species. We encourage CVM to work closely with the Minor Animal Species Health Coalition to accomplish this objective.

Should products be labeled to reflect the use of different standards? If not, why not?

We would oppose the general labeling of products to reflect different standards, since we still expect the products that are made available to have the same degree of safety. If a subsequent recommendation is implemented, to provide for a streamlined approval process followed by post-market surveillance, we recognize that there would be a need to indicate the conditional status of the product.

While not related directly to different standards, we believe that the labeling of drug products for minor species should be as broad as possible and make use of broader groupings. In aquaculture, there are 20 different species of trout, that under current law requires separate INAD/NADA and separate labeling. Consideration be given to grouping of like species, so that information gathered for one species would apply to all like species.

If the act were amended to permit FDA to approve new animal drugs for a minor species or minor use under different standards, how would appropriate doses be determined and how would residue depletion and withdrawal times for food animals be determined?

The comments of the National Aquaculture Association provide several useful suggestions in this area. We encourage CVM to give these recommendations serious consideration.

On the human drug side, certain critical drugs for life-threatening and serious diseases are approved through an accelerated approval process in which follow-up studies are required to confirm approval (see 21 CFR part 314, subpart H). Similarly, section 522 of the act (21 U.S.C. 360l) requires and authorizes the agency to require postmarket surveillance of certain devices to protect the public health or provide safety and effectiveness data. Would sponsors and users accept conditional approvals and postmarket surveillance as a tradeoff for requiring less in the way of premarket target animal safety and effectiveness studies for new animal drugs for minor species or minor uses? Should a drug approved under such a mechanism bear labeling that reflects its conditional status?

This appears to be a useful and effective way to speed access to needed products. Farm Bureau would support a streamlined approval process, followed by post-market surveillance. We would recommend that the agency give serious consideration to the American Sheep Industry Association comments in this area.

Should the act be amended to allow FDA to accept foreign reviews or approvals of new animal drugs for minor species or for minor uses?

Foreign reviews of new animal drugs for minor species should be accepted if drugs have gone through a valid, science-based registration process in another country. We would also recommend that strong consideration be given to utilizing existing data from the labeling process in these countries in the development of labels for use here.

AFBF policy recommends that "FDA use scientific research data of foreign countries to assist in approving animal health products for use in the United States and to help ensure international uniformity in standards for pharmaceutical approval." AFBF also supports, "Federal regulations and programs which will encourage greater uniformity among states and countries in the testing and health requirements necessary for interstate and international transportation of livestock and exotic animals and birds."

How should Congress or FDA determine whether the reviews or approvals of a particular country or countries are acceptable as a basis for approval of uses for minor species or for minor uses.

This would need to be determined on a country-by-country basis.

Could determinations of animal safety and effectiveness by expert panels or compendia be used to support drug approvals for minor species and minor uses? If so, what information would serve as the basis for such determinations? Should the determinations of these panels or other information be used to issue monographs or similar standards? Who would

draft monographs or similar standards and why?

This would seem feasible. Data gathered from approvals for major species, other minor species or that published in peer reviewed scientific journals could be used.

C. Administrative and Regulatory Changes

Would a strategy similar to that used by the agency to facilitate drug approvals for some aquatic species be successful if extended to other minor species? That strategy includes coordination of investigational new animal drug (INAD) information collected or generated by end users. It also includes a centrally-organized and CVM- operated field education program directed at end users as potential INAD sponsors. In which species/uses would such an approach work or not work? Why?

The strategy is sound and based on information we have received appears to be starting to move products through the approval process for aquatic species. For such a strategy to be successful, it does require cooperation on the parts of all users involved. Every effort needs to be made to encourage such cooperation from all parties, including other federal agencies. If other regulatory constraints make such cooperation problematic, they should be reviewed and modified as needed.

D. Creating Incentives

Would economic incentives, such as tax breaks, grants, and periods of market or label exclusivity, encourage the pursuit of approvals or supplemental approvals for labeling modifications for minor species or minor uses? If so, what kinds of incentives would be most effective?

We would support the establishment of economic incentives for drug clearances; however, we would note that such incentives need to be meaningful and long term if they are to be effective. We would not support incentives that would increase cost for producers of major species to supplement to cost of approval for minor species.

If producer groups or other organizations were willing to conduct or otherwise fund studies to demonstrate safety and efficacy for new animal drug approvals for minor species or minor uses, would sponsors be willing to use the data from the studies to support approvals and new or revised labeling? If not, why not?

We would encourage producer groups and organizations to conduct such work. We recognize that it would need to be done in a manner that would insure its validity if it were to be used in the approval process.

Should a program similar to the U.S. Department of Agriculture's National Research Support Program #7 (NRSP-7), which currently funds studies for minor use therapeutic

uses for food- and fiber-producing animals, be developed for wildlife and zoo animals and/or for production uses? Should the NRSP-7 program be expanded to cover such uses?

The NRSP-7 program is serving a useful function. We would support expanding the existing program rather than initiation of a new program.

Could and should philanthropic, public interest, or other not-for-profit organizations be encouraged to fund research for the development of new animal drugs intended for use in minor species or for minor uses? If so, how, and by whom?

We would encourage such efforts.

E. Extending Existing Legal Authority

Would legislation be desirable to extend the AMDUCA to permit extralabel use of: (1) Medicated feeds or (2) reproductive hormones and implants? What are the pros and cons of approval versus extralabel use under the AMDUCA?

As noted previously, we would support expansion of the VFD to cover minor species and uses. We would also support the concepts suggested by the American Veterinary Medical Association on this issue that would not require revisiting AMDUCA.

We appreciate the opportunity to comment on this docket. We look forward to working with FDA/CVM over the coming months on the implementation of an improve process for the approval of animal drugs for minor species and uses.

Sincerely;



Richard Newpher
Executive Director
Washington Office