UNIVERSITY OF
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Friday, 5th September 7, 1997

Dockets Management Branch [HFA-305]
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville MD 20855

To Whom it May Concern:

Comments on Encouraging Animal Drug Approvals for Minor Species & Uses

I would like to reply to your agency's request for comments and suggestions on options to encourage animal drug approvals for minor species and minor uses. In doing so I would advise you I am a veterinarian employed at a College of Veterinary Medicine and the Southern Drug Coordinator in the NRSP-7 program. The views I am expressing here are my own and do not necessarily reflect those of my Institution or of the NRSP-7 program.

My paramount request is that any changes in the approval process do not create second class drugs with inferior background. As most of the drugs for which minor species approval has been sought represent label extensions there should be a lot of background information relating to approval criteria available that creates a better comfort zone. It is when novel drugs come to the approval process and there is minimal safety and efficacy data available that the FDA must work to maintain standards.

I believe the major problem facing drug approvals in the minor species is the cost involved and the lack of incentive for pharmaceutical manufacturers and primary producers to be come more than peripherally involved. There are a number of incentives that could become available to manufacturers. These incentives could include tax breaks on either the product being approved or a selected spectrum of the manufacturer's product line, exclusivity and/or patent extensions,

Likewise when cooperation of primary producers is sought it is often given reluctantly as it is perceived that there is nothing in it for them. This then requires bodies such as NRSP-7 conducting pivotal studies to buy animals and house them away from a normal commercial setting. This puts strains on such bodies' financial resources by increasing the cost of approval studies and may lessen the value/validity of the study's findings. If producers were able to have some form of tax advantage from participating in studies it would make them more willing to collaborate. The question of how good would data be when collected by producers

[redacted]

However in cases where there is no alternative available to a veterinarian in treating sick animals a means must be made to expedite approval of commonly accepted and safe drugs or to allow dispensations under a mandated program. I would have problems in such approval/dispensation being allowed in the case of hormones and reproductive drugs given the multigenerational effects of DES that we still face. These agents need the benefit of full review and consideration.

Yours truly,

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