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Subject: Comments on "Minor Species" draft  
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January 19, 1998  
Center for Veterinary Medicine  
Food and Drug Administration  
Rockville, Maryland

Re: Comments on "Discussion Draft: Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses"

In general, I support, commend, and applaud the efforts of CVM to address the problem of lack of availability of pharmaceuticals in minor species. Please accept these comments pertaining to some specific areas of the draft document.

Page 7 Section entitled: "A. Modification of Extralabel Provisions" and page 19: "Extra-label drug use of a conditionally-approved minor use drug product would not be permitted.

Many other countries (eg; Canada) appear to give the veterinarian both more responsibility and liability in the extra-label process. This does not appear to be a disincentive as many pharmaceutical companies still view the US as one of the most burdensome systems to register a pharmaceutical and will often register a product in other countries first, or forego US application all together. For many "minor species" (eg: aquaculture), other countries appear to have both more licensed pharmaceuticals TOGETHER with more veterinary extra-label latitude. I do not think that extra-label use has been shown to hinder the process or availability of licensed products. There is too much financial incentive for pharmaceutical companies to achieve non-prescription status.

Certainly, the FD&C Act should be modified to allow extra-label use of medicated feeds and extended to include reproductive hormones and implants. It should also be modified whereby greater veterinary latitude is tiered based upon greater responsibility. In other words, there could be greater requirements for veterinarians based upon "classes" of extra-label use. The current requirements of valid client-patient-vet. relationship; emergency use; etc. could still apply as currently used, however, for other pharmaceuticals or uses, monitoring, recording, and/or reporting requirements could be more stringent. For example, a licensed prescribed "extra-label" in a closely related species would require much less veterinary monitoring and reporting than one which was not licensed in a closely related species and/or through an alternate method of application. Consequences for veterinary non-compliance could be defined in statutes.

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Page 9: Section on "Removal of Disincentives"

Although reasonable in theory, it is questionable as to how much of a disincentive the lack of enforcement against those firms which market unproved drugs, really is. If a pharmaceutical company sees a potential market, they will weigh the costs and benefits of development and registration. If there is an illegal product as a competitor, then they will certainly and repeatedly bring it to the attention of CVM, as well as the company that is in violation. This is more of an enforcement issue and should not be part of proposals to increase minor species pharmaceutical availability.

In general, the proposals presented in the draft are excellent initiatives and will be greatly welcomed by companies and individuals involved in minor species. If not already done, there should be an exhaustive review of how use and approval for minor species drugs is done in other countries. Approaches should be summarized as to their pros and cons and those that may be relevant, amended to the draft. In doing so, it is important to look at the cause and effect of other countries policies. Do more stringent guidelines and regulations result in greater food safety together with more efficient and humane minor species production in those countries. We should be careful to assume that different policies produce different effects. The effects are what should be concentrated on.

Please feel free to contact me with any questions or comments.

Sincerely,

Hugh Mitchell, MS, DVM  
Development Manager  
Alpharma Aquatic Animal Health Division