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Comments on Docket number 97N-0217
"Discussion Draft - Proposals to Increase the Availability of approved Animal Drugs for Minor Species and Minor Uses"

I am George C. Scott DVM. I have almost 40 years of industrial experience from clinical field trial development to Vice President of R+D of a major Animal Health Company. Since my retirement I have consulted for a number of major companies in the Animal Health field.

Since 1993 I have been majorly involved in 2 drugs seeking clearance for minor conditions in minor species.

The first project I supervised and participated within was for an anesthesia condition in mink which affects 3-5% of mink population. The drug has been used in many international countries in a number of species for anesthesia. A number of foreign publications were available as well as considerable literature in mink.

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At this time the agency requested a dose-range study, for which we submitted published data.

The most unreasonable request was for the safety study. Too many dose levels at too long of interval of treatment on a drug which had extensive data in a number of species. (It was already cleared in the US in combination with another drug for use in swine)
Extensive ~~pathology~~ histopathology of all dose levels of the reproductive tract.

Although the drug was being sold in US in combination with another drug, it was necessary to submit a full blown NADA on manufacturing and quality control.

This drug is still not cleared for use in men in the US as more requests are being made by the agency.

The second study I supervised was for use of a drug in fish for enhancing reproductive performance of "game" fish at fish hatcheries. In all, over 10 state fish hatcheries in the southeastern US participated in this study. I visited each site. In most cases the study was at various stages of completion.
This drug had been used a number of years at all these locals either illegally or under a so called INADA. These reasons had worked out their own dose levels and intervals of treatment. Many of the investigators had published reports of their previous work with this drug, most of them has BS some a MS in the fish field.

most had never participated in a well designed and controlled study in which a uniform system was utilized.

Data will never be developed in these species with drug as would be presently required for a food producing animal.

The agency must remove disincentives for pursuing minor use/minor species.
Safety and efficacy in other species must play a major role and the agency must extrapolate from these other species to the maximum.
Well designed controlled studies are always needed.
Extensive toxicity studies aren't always needed.
Scientists within the agency must be very flexable and not always apply the same routine requirements.

Another major problem within the agency is that reviewers assigned to the proposed drug development projects are assigned to the project because they are in the section that is charged with handling drugs in this area.

None of reviewers on the menk ~~project~~ NADA had ever been on a menk farm. None were acquainted with this drug. Others in agency were familiar with drug and other may have been acquainted with the menk industry

The same is true of the fish project.
Personnel within the agency familiar with the minor species or minor indication should assigned to its review.
Other familiar with the class of drugs should be assigned to the review also.

On older drugs going into minor species or minor uses "conditional approval" should allowed.
This is especially true when the drug has been approved in other countries or drugs used in this country in which data can be extrapolated from publications or "good common sense."

In my opinion both of these drugs should have been "conditionally" approved while more data was be developed.
The agency already allows human drugs to be used "extra label" in small animals.

Each drug should be considered for extra label use in all species for minor indications based on its known pharmacological actions.

I heartily endorse the use of expert review panels similar to those in the human area. This is very important when there is a lack of knowledge

within the agency. Fish a minor species is an excellent example — birds — snakes, bananas and many more could use expert panels.

International harmonization should be implemented. A minor species in U.S. may not be so minor in other countries.

Data development is very challenging in many minor species. Both the agency, USDA and industry must combine efforts in this area.
A collaborative effort could be set up for each minor species

I personally don't believe in "orphan drugs" and don't support such a program.

The agency encouraged the clearance of the drug for fish however this did not help with the reviewing personnel. Based on knowledge and experience with this drug at the "fish hatchery level" this drug was an excellent candidate for "conditional approval" or extra label use.

I urge the agency to consider both of these provisions for drugs use in minor species and for minor conditions.

I urge the agency to use its personnel more effectively by assigning personnel to drug review who are most knowledable of the minor species, the minor indication and the drug itself

I urge the agency to use expert panels for minor species and minor use on major species.

The implementation of these four areas will result in real incentives for industrial clearance of more drugs for minor species and minor use.

All the past actions, incentives and proposals has resulted in very limited action in this area.

Thanks for the opportunity to comment

George C. Scott DVM

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