



Texas Agricultural Experiment Station

The Texas A&M University System

Office of the Texas State Chemist

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

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Dear Messrs/Madames:

The Office of the Texas State Chemist wishes to offer written comments relating to the legislative and regulatory options to facilitate the approval of new animal drugs intended for use in minor species or intended for minor uses.

The Office of the Texas State Chemist is constituted under Section 4 TAC 141 of the Texas Agricultural Code and is charged with the responsibility of administering the Texas Feed Law. This administration includes, in part, the regulation of medicated feeds; thus, the final answers to the questions asked directly affect the ability of the Office to perform its function under the Texas Commercial Feed Control Act (4 TAC 141).

I offer the following comments:

1. Standards for target animal safety and effectiveness and for the production of new animal drugs should remain the same. Regardless of how carefully drugs are administered, there is always a tendency to push limits. Even though human consumption of minor species may be small, no risk whatsoever should be taken beyond those associated with drugs for other food animals. Nor should the standards for minor species drugs differ depending upon the species. Any particular use which differs from these standards can be administered under a veterinary feed directive or under extra label drug use. Nor should there be different standards for the manufacturing of drugs for minor species or minor uses.
2. The Food and Drug Administration should accept approvals of other governments with reputable review agencies of new animal drugs for minor species and minor uses. Results reported in peer-reviewed journals which withstand inspection by the Food and Drug Administration should be given the same credence we would give equivalent studies in the United States. It is immaterial whether reviews be done by expert panels or within the Agency;

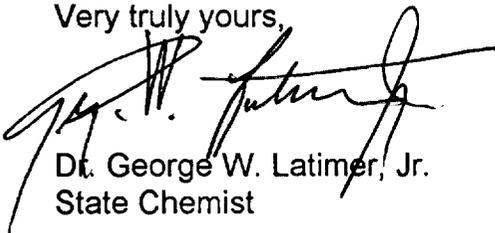
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however, I recommend that the FDA designate panels to review a given drug and allow the company sponsoring the drug to pay for the time that these individuals invest in the project.

3. The Agency should accept as valid studies done on species which are sufficiently related that cross-breeding produces fertile progeny.
4. Economic incentives should not be offered to the public. The marketplace should be governor of whether a study should be made; however, the FDA should provide estimates of the expense of conducting a trial and allow those who are interested in the product, regardless of whether they are consumer or producer, to contribute to a designated fund until there is enough money to pay for the study. It is my firm belief that if the regulations are clear and straightforward, the cost will not be extraordinary.
5. Once the FDA has decided upon an appropriate mechanism for approving these drugs, it should provide a step-by-step set of instructions including where an individual should write, what minimum amount of data under what kind of design is needed so that those who are inexperienced can devise a program which will meet the regulatory requirements. At the present time, it is very difficult for those unused to dealing with the Food and Drug Administration to determine precisely what the Agency requires.

Very truly yours,



Dr. George W. Latimer, Jr.
State Chemist

cc: Mr. Roger Hoestenbach

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