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Dr. Margaret Miller  
HFV-1, Room 482  
FDA, Center for Veterinary Medicine  
7500 Standish Place  
Rockville, MD 20855

Re: Proposed Framework for Evaluation and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for use in Food Producing Animals.

Dear Dr. Miller:

This proposal will eliminate future development of antimicrobials for use in food producing animals due to long term development and cost. It does not take into consideration that there is no such thing as "no risk" in this life. As late as 1998, the NRC stated that, "...regulating antibiotics cannot be implemented through science – driven, well-validated and justified process." The development of antimicrobial resistance is a potential hazard that does not necessarily translate into a risk. Resistance has been developing in bacteria since long before antibiotics were discovered. It is a natural phenomenon. Antibiotics for economical food animal production are absolutely essential.

There is no scientific evidence that antibiotic use in food animals constitutes an eminent public health risk. The Georgetown University risks and benefit assessment study will be completed later this year, and this proposal can certainly wait until that study results are available. There are no documented cases of human diseases not being effectively treated due to resistance from the use of antibiotics in food animals. There are reports where this is theorized, but not scientifically documented.

Foodborne diseases caused by major zoonotic pathogens are actually decreasing in the United States. The AVMA "judicious use of antibiotics program" and HACCP, which have been implemented by FSIS, will reduce the need for more stringent regulations. The long history of antibiotic use in food animals has failed to reveal any examples of a negative impact on human health. Biosecurity, sanitation and good management practices used in food animal production will greatly reduce the use of antibiotics in food animal production.

98D-1146 Specialty Products Division

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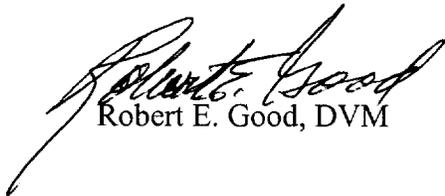
The fluoroquinolone risk assessment has shown no resistance development. A study revealed that fluoroquinolone resistant campylobacters has been increasing since 1991 which was four years before approval of fluoroquinolones in food animals. In the proposal, vancomycin resistant enterococcus (VRE) is listed as an example of antibiotic resistance due to use in animals. While VRE is a problem in both the United States and Europe, no glycopeptide antibiotic has ever been used in the United States animal agriculture.

This proposal is unnecessary at this time. Better use of resources is a risk assessment study. My recommendations are:

1. A scientific risk assessment
2. Risk characterization of the issue
3. More data from the NARMS program
4. Involvement of all stake holders in future proposals

I respectfully request that this proposal not be implemented until more scientific data is available to substantiate a real threat to human health.

Sincerely,



Robert E. Good, DVM