



California Prime Poultry

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

March 19, 1999

Dear Dr. Miller;

As a practicing poultry veterinarian, I find the "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" alarming.

Please consider the following:

- The connection between abuse of antibacterial drug usage, humans especially children and developing resistant strains in humans has much more significance. As a mother, I can cite numerous times my children were given antibiotics by "phone visits" and the times friends have told me they were given antibacterial drugs for colds or the flu. Many times antimicrobial prescriptions are discontinued before the effective treatment term or are taken only sporadically or for daylight hours only. These practices create resistant strains among humans.

The correlation between antimicrobial use in poultry and resistant bacterial strains in humans has not been proven. Have you looked at the connection to companion animals and resistant strains created by antimicrobials given haphazardly by owners?

To make the approval of antimicrobials for use in food animals more difficult or costly is to effectively shut down the application process. Already, any recently-approved drug is priced out of production's range due to the cost of obtaining approval through FDA versus the amount that must be charged over the run of the patent to recoup the investment. New and useful drugs do not reach the food animal market because it is too costly to get approval and the market is too small to make a profit. As a veterinarian, I am truly concerned. Not every flock of chickens can be raised without health challenges and this even with the best management and preventive

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medicine. Without these tools to use which are placed in the hands of responsible, trained, licensed professionals, the food animal industry goes back to primitive medicine - before the dawn of science. Truthfully, this is appalling.

We are concerned with resistance building, especially in humans but also in our animals. Therefore, the food animal veterinarian uses antibacterial drugs in a judicious manner. We aim for healthy animals through good management and the practice of preventive medicine. Any medication we use decreases profitability so, we must and do minimize the use of medication.

I understand there is a risk assessment study being conducted at Georgetown University. Would it not be prudent to wait for the completion of this study before proposing significant changes in evaluations, etc? It appears the CVM is wanting these changes regardless of what science or objectivity provides to the consideration.

We are all concerned with antimicrobial drug resistance, but we should consider the most probable source or at least wait for the information to provide guidance in establishing controls.

Thank you for your time and consideration in this matter.

Sincerely,

A handwritten signature in black ink that reads "Cheryl Hall, DVM". The signature is written in a cursive, flowing style.

Dr. Cheryl Hall, DVM, MAM, ACPV.