

October 14, 2004

Dr. Lester Crawford, Acting Director
Food and Drug Administration
5600 Fishers Lane, Rm 1471
Mail Stop HF-1
Rockville, Maryland
20857

Dear Dr. Crawford:

I am writing to you as a fellow veterinarian to express my concern about the FDA's CVM proposal to withdraw approval for the use of enrofloxacin in poultry. I would like to start by stating that I have worked with the poultry industry since 1993 and there is nothing else I would rather do. I made a commitment to a career in poultry medicine while a veterinary student at Purdue University. I was most impressed by the poultry industry as a model for population health where the emphasis was on disease prevention rather than treatment. The emphasis on disease prevention was the natural outcome of the interaction between veterinarians, poultry scientists and an industry operating under an efficient and mature agribusiness model.

Even when operating under a strong emphasis on prevention, occasionally poultry veterinarians need effective antibiotics to treat systemic bacterial infections that pose a threat to the flock's health and welfare, and the livelihood of the farmer. Colibacillosis is such a threat and enrofloxacin is the last resort and most effective antibiotic against colibacillosis available in the United States. Enrofloxacin is used judiciously because it is a prescription-only antibiotic and it is costly. In my experience, enrofloxacin is prescribed based on lesions, isolation of *E. coli* from the lesions and antibiotic susceptibility results. Poultry companies are not in a rush to use enrofloxacin because they operate under a business model that will not allow it unless warranted. Based on my international technical service and consulting travels, I know that antibiotics, including fluoroquinolones, are not used as judiciously in other countries.

In recent years the poultry industry has been "targeted" by a powerful issue triad consisting of food safety, animal welfare and environmental concerns. Our society has ample food sources and the poultry industry evolved to satisfy society's demands. My concern is that today the industry and consumers coexist in what I perceive is a chasm between science and activism. Europe's precautionary principle appears to be attractive to some in the United States. Live bird markets, organic poultry and free-range practices have gained popularity with a few consumers, but in my opinion are a step backwards in food safety and disease prevention.

I have followed the antibiotic resistance issue and the FDA's efforts to withdraw approval for the use of enrofloxacin in poultry closely enough to know that the FDA has received ample scientific evidence to consider. That is why in my letter I decided to concentrate on "big picture" items. I urge the FDA to consider all the scientific evidence

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and to assess the impact of withdrawing enrofloxacin. Large numbers of sick or dead poultry are not in the best interest of food safety, animal welfare or the environment.

Congratulations on your ascent and accomplishments at the FDA. Your career is a testament of the versatility of our profession and serves as inspiration to all veterinarians.

Sincerely,

A handwritten signature in black ink, appearing to be "José A. Linares", written over a horizontal line. The signature is stylized with loops and a long horizontal stroke extending to the right.

José A. Linares, DVM, ACPV
Resident Director
Texas Veterinary Medical Diagnostic Laboratory
Poultry Diagnostic Laboratory
Gonzales, TX 78629

cc: Dockets Management Branch, ref# 00N-1571