

August 23, 2004

Dr. Lester M. Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

09-22-04 P02:22 RCVD

Dear Dr. Crawford:

I am writing to you to ask you to oppose the recent rule of FDA's Administrative Law Judge Davidson in regards to the ban of enrofloxacin, (Baytril®), the only fluoroquinolone approved for the treatment of various bacterial infections in poultry.

I have been involved in poultry medicine since the beginning of my career in 1978. I hold a Doctor of Veterinary Medicine degree, a Master of Poultry Science degree, a Certificate of Internship in Avian Medicine and I am Board Certified by the American College of Poultry Veterinarians. I also serve since 1995 as an Adjunct Professor in the Department of Avian Medicine at The University of Georgia College of Veterinary Medicine.

First of all and of extreme concern, judge Davidson ignored all the scientific evidence presented during the open hearing by Bayer's expert witness that clearly showed through a quantitative risk assessment that the potential contribution of Baytril® use in poultry to antibiotic resistance in human campylobacteriosis is negligible.

Secondly, the data collected by both, USDA and CDC through the National Antibiotic Resistance Monitoring System clearly shows that there is no correlation between antibiotic resistance patterns or trends in human and poultry isolates of *Campylobacter spp.*

Thirdly, enrofloxacin, Baytril®, is only used in poultry when bacterial isolation and antibiotic sensitivity testing shows that it is the only effective treatment. Baytril® can only be used by prescription by a licensed poultry veterinarian with strict adherence to withdrawal requirements. Records must be kept for a number of years in all cases where Baytril® has been prescribed. All of these requirements in addition to the high cost of this medication compared to others aid in ensuring that this drug is only used very judiciously, basically only when nothing else works, and for the purpose of relieving animal suffering and catastrophic losses to poultry producers. I believe that not more than 1% of all chickens produced in the United States every year get treated with Baytril®, and even in turkeys, which have a much longer production life and are more commonly afflicted by bacterial infections, I believe that Baytril® is used in less than 5% of all the turkeys produced each year in the United States. However, in cases of systemic bacterial infections that do not respond to other drugs it is critically important to have a therapeutic alternative like Baytril®.

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The fear of antibiotic resistance transmission from animals to people via the food chain has been overplayed and sensationalized by the media and the activist groups opposed to antibiotic use in food-producing animals. Realistically speaking society would be much better served if agencies like FDA, CDC and USDA spend more time and resources educating people and restaurant owners about the importance of good hygiene habits in the kitchen and on adequate cooking temperatures. Dead bacteria can not transmit antibiotic resistance so any illness-causing bacteria acquired by eating food indicates a lack of proper hygiene in the kitchen, or consumption of food that has been improperly stored or cooked.

I have always been encouraged and proud of FDA's position in letting the science prevail over the politics and the personal agendas. I hope that the final ruling on the future availability of Baytril® to the poultry industry will be based on conclusive scientific evidence and quantitative risk assessments continuing on with a long tradition of science and fairness.

Respectfully,



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CC: Dockets Management Branch, ref. # 00N-1571

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