

August 4, 2004

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

Dear Dr. Crawford:

Please vigorously 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 am especially concerned about the process by which FDA's Center for Veterinary Medicine (CVM) is proposing to withdraw approval for the use of a fluoroquinolone (enrofloxacin) in poultry. Please consider the scientific evidence on both sides of this issue.

I speak as a professional and a citizen. I am a 1989 Doctor of Veterinary Medicine graduate of NCSU-College of Veterinary Medicine. I specialize in providing services to the poultry industry. The treatment and control of disease in animals is critically important to the health and welfare of the animal and to the safety of the food produced. Antibiotics have been used safely for more than 40 years to maintain animal health.

- I am very concerned that the Judge dismissed the testimony of Bayer's expert witness, Dr. Cox, as unreliable. Please objectively reconsider this data.
- FDA is considering Baytril withdrawal for both chickens and turkey labels, based strictly on chicken data alone. This is contrary to the species-specific approval process of FDA.
- The Judge did not study the public health benefits realized from the use of fluoroquinolones in poultry.
- Scientific evidence was presented and not considered showing through a quantitative risk assessment that the potential contribution of Baytril use in poultry to antibiotic resistance in human campylobacteriosis is negligible.
- 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.* Resistance data indicate the incidence in humans of campylobacteriosis decreased from 2.4 million cases to 1.4 million cases the first three years the drug was in use. More significantly, the incidence of fluoroquinolone-resistant *Campylobacter* infections in humans decreased from 3.28 to 2.62 cases per 100,000 population between 1997 and 2001.

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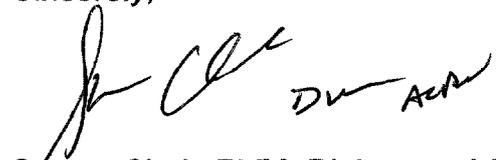
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- There are effective alternatives available to treat campylobacteriosis in humans; there are not effective alternatives for treating the labeled indications in poultry (contrary to the administrative law judge's remarks).
- Fluoroquinolones are used extremely sparingly in the turkey industry; less than 5% of all turkeys produced in the United States ever receive fluoroquinolones.

My credentials include being a highly specialized Doctor of Veterinary Medicine and a Board Certified Diplomate of The American College of Poultry Veterinarians with 14 years of experience with the food animal industry. Animal drugs are vital tools for veterinarians, livestock and poultry producers to maintain animal health and safeguard our food supply. I hope you will do all you can to oppose this measure, and I look forward to hearing from you. As an animal health professional I am here to help --- please contact me if I can provide you with more information or assistance.

Sincerely,



Steven Clark, DVM, Diplomate ACPV
Technical Service Manager, Poultry
Alpharma Inc.

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

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