

AVTP

1316 Merrywood Ct.
Faribault, MN 55021

Sept 9, 2004

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

Dear Dr. Crawford,

The Association of Veterinarians in Turkey Production is an organization that consists of veterinarians who specialize in turkey medicine. The companies that employ our members represent over 75% of the turkey production in the United States. Without question, there is no other body in the U.S. that has as much clinical expertise and practical experience in the specialty of turkey veterinary medicine than the AVTP membership.

We are writing with regards to the Fluoroquinolone issue, which is being considered by your office. The membership of AVTP is concerned that we are in danger of losing enrofloxacin, **the only effective treatment** for most colibacillosis infections in turkeys. Although there are other antibiotics such as oxytetracycline that are labeled for *E. coli* infection in turkeys, after 60 years of existence these antibiotics are simply no longer effective against *E. coli*, the most common infection of turkeys. In cases with high mortality, enrofloxacin is truly our drug of last resort.

Whether intentional or unintentional, there is much misinformation being disseminated by groups that are advocating the removal of enrofloxacin in poultry. Let us set the record straight. This drug is used **only** in the drinking water, never in feed. This drug is used only under the authority of a licensed veterinarian. Enrofloxacin is very expensive and, as stated earlier, it is used as a last resort and only for the most difficult cases. Less than five percent of turkey flocks are treated with enrofloxacin.

Much of the data from which Center for Veterinary Medicine has based its case is derived from chickens. While we believe that the conclusions drawn by CVM about this chicken data are wrong, we are also concerned that CVM is ignoring one of its own policies. Since CVM has never allowed a drug sponsor to extrapolate between species during the drug approval process, that same standard should apply to CVM when attempting to withdrawal a drug.

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We have reviewed the CVM's case for removal of enrofloxacin and it is filled with errors, assumptions and speculation. For example, the data regarding *Campylobacter* resistance are questionable, especially since most of the information was derived from *Campylobacter coli*, not *Campylobacter jejuni*, which is the *Campylobacter* species that causes most foodborne illness in humans. Also, foreign travel, which is one of the most common risk factors associated with fluoroquinolone resistant-*Campylobacter* in humans, was virtually ignored as a significant cause of resistance.

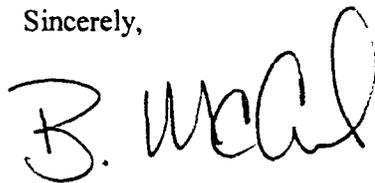
The AVTP feels that this issue has been mishandled from the publication of the original NOOH in 2000. We believe the preponderance of evidence available then, as now, indicates that fluoroquinolone use in poultry is having no impact on human health, nor is it likely to ever have an impact. Resistance data indicate that the incidence of fluoroquinolone-resistant *Campylobacter* infections in humans actually **decreased** from 3.28 to 2.62 cases per 100,000 people between 1997 and 2001.

While we are reluctant to acknowledge the European Union's track record on antibiotic use in food animals, it is especially significant to note that the **EU nations that have led the way in curbing antibiotic use in food animals have found that enrofloxacin use in poultry poses no significant threat to humans.** This is from the same people that brought us the "Precautionary Principle", where feelings and fears about technology always trump science.

We understand that there is immense pressure from consumer activists and the medical community to remove this valuable veterinary drug. Unlike the European Union, the FDA has traditionally relied on hard science and not politics to make decisions that affect human and animal health. The members of the AVTP request that FDA continues that tradition of relying on science instead of fear when making this important decision.

We strongly urge FDA to consider all of the evidence in a scientific manner by appointing an independent panel of experts that includes representation by poultry veterinarians. We believe a truly scientific review will not support the withdrawal of enrofloxacin in poultry.

Sincerely,

A handwritten signature in black ink, appearing to read "B. McComb". The signature is written in a cursive, somewhat stylized font.

Brian McComb, D.V.M.
President, Association of Veterinarians in Turkey Production

cc: Food and Drug Administration
Dockets Management Branch
Ref. Docket # 00N-1571
5630 Fishers Lane
Room 1061
Rockville, MD 20857