

# 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.

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.

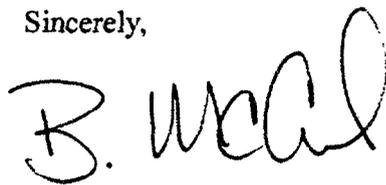
The AVTP feels that this issue has been mishandled from the publication of the original NOOH in 2000. We believe the preponderance of evidence available then, as now, indicates that fluoroquinolone use in poultry is having no impact on human health, nor is it likely to ever have an impact. Resistance 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 fluid and cursive, with a large initial "B" and a long, sweeping tail.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville MD 20857

September 29, 2004

Brian McComb, D.V.M.  
President  
Association of Veterinarians in Turkey Production  
1316 Merrywood Court  
Faribault, Minnesota 55021

Dear Dr. McComb:

Thank you for your letter of September 9 addressed to Dr. Crawford regarding the proposed withdrawal of the approval of enrofloxacin use in poultry. As described below, this matter is now pending before Dr. Crawford.

Under longstanding federal regulations governing the withdrawal of approval of a new animal drug, communications about this proposed withdrawal are not allowed between the Commissioner, officials advising the Office of the Commissioner, and persons outside the Food and Drug Administration (FDA). See Title 21 Code of Federal Regulations, Section 10.55(d)(1) (21 CFR 10.55(d)(1)). Therefore, Dr. Crawford is unable to respond to the specific issues regarding enrofloxacin that you raise in your letter. For your information, under these regulations, a copy of your correspondence and this response must be placed in the FDA docket and served on the participants. See 21 CFR 10.55(d)(3).

However, I am able to provide the following information on the regulatory process for FDA's formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. The FDA's formal hearings are conducted by an administrative law judge under regulations found at 21 CFR part 12. These regulations set out the procedures that FDA must follow when conducting formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of the New Animal Drug Application (NADA) 140-828, pursuant to Section 512(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act. That section requires that a new animal drug must be shown to be safe and effective for its intended uses. On October 31, 2000, CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register*. On November 29, 2000, Bayer filed a request for a hearing. The FDA Commissioner agreed and published a Notice of Hearing on February 20, 2002, in the *Federal Register*.

After submission of documentary evidence, written direct testimony, and joint stipulations by CVM, Bayer Corporation, the sponsor of the animal drug, and non-party participant Animal Health Institute (AHI), an oral hearing for cross-examination of witnesses was held between April 28 and May 7, 2003, with Administrative Law Judge Daniel J. Davidson presiding. The parties and AHI filed post-hearing briefs and replies in the summer of 2003 and the

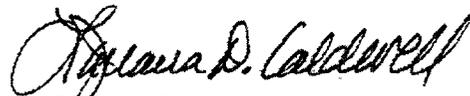
Page 2 – Dr. Brian McComb

administrative law judge issued an initial decision on March 16, 2004. The parties have filed exceptions to the initial decision.

A public docket was established at the time the NOOH was published in October 2000. The record of the hearing, which includes the NOOH, referenced scientific studies, briefs, hearing transcripts, the initial decision of the administrative law judge, and subsequent filings by CVM, Bayer, and AHI, can be found in this public docket (Docket No. 2000N-1571).

I hope this information is helpful. Thank you for your interest in this issue.

Sincerely,



Lajuana D. Caldwell  
Director  
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)