



# Sietsema Farms

July 28, 2004

Office : 11304 Edgewater Dr. Suite A, Allendale, MI 49401 Phone : (616)895-7493 Fax : (616)895-4008  
Farm : 11655 56<sup>th</sup> Ave., Allendale, MI 49401 Phone : (616)895-4260 Fax : (616)895-4262

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

Dear Dr. Crawford,

The National Turkey Federation represents all segments of the turkey industry including processors, growers, breeders, hatchery owners and allied companies. NTF is the only national trade association representing the turkey industry exclusively. Our members have worked closely with Congress and FDA over the years to create an environment in which safe, effective animal drugs can be approved in a science-based, expeditious manner. Our members are extremely concerned about the process by which FDA's Center of Veterinary Medicine (CVM) is proposing to withdraw approval for the use of a fluoroquinolone (enrofloxacin) in poultry.

Fluoroquinolones are used extremely sparingly in the turkey industry – less than 5 percent of all turkeys produced in the United States ever receive fluoroquinolones. The cost of the drug and the industry's tight operating margins require our members to use this as a drug of last resort. But, when fluoroquinolones are used, they are absolutely essential. If our members could not administer the drug in those instances, they would suffer significant losses in their flocks. Contrary to the administrative law judge's initial decision in this case, there are not effective alternative treatments available.

NTF's members have felt this regulatory issue has been mishandled from the publication of the original Notice of Opportunity for Hearing in 2000. We believe the preponderance of evidence available then, as now, indicates fluoroquinolones use in poultry is having no impact on human health, nor is it likely ever to have an impact. 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. Finally, there are effective alternatives available to treat campylobacteriosis in humans, which – as we have noted – is not the case in turkey production.

In February 2001, NTF filed comments with FDA urging the agency to halt its regulatory activity against fluoroquinolones. Absent that action, we asked FDA to grant the manufacturer a hearing, which FDA consented to do. We believe the evidence presented at the hearing raised serious doubts about the validity of FDA's case, and we believe the administrative law judge made several erroneous rulings in his initial decision. We

2000N-1571

C 284

believe there is sufficient evidence to indicate the judge made errors on such key matters as the likelihood of transferring resistant *Campylobacter* infections from poultry to humans, the incidence of fluoroquinolone – resistant campylobacteriosis in humans, the duration of illness for people who contract resistant campylobacteriosis and the public health benefits realized from the use of fluoroquinolones in poultry.

However, our biggest concern with the judge's initial decision is the problem we have had from the outset of this case. When FDA first proposed withdrawing approval of fluoroquinolones in poultry, it did so based strictly on studies conducted in chickens. This simply is unconscionable and directly contradicts more than 40 years of policy at the agency. FDA officials have long held that a drug could not be approved for use in turkeys based solely on data collected in chickens. The agency contended that there are too many physiological differences between the birds to treat a turkey like a "big chicken". Now, the agency is saying that its long-held position does not apply to the withdrawal of a drug. This borders on being hypocritical.

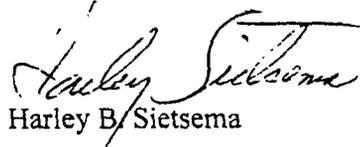
If the agency now contends it can withdraw approval for a turkey drug based strictly on chicken data, then we do not see how the agency has any legal choice but to begin approving turkey drugs based solely on chicken data.

When the agency first approved fluoroquinolones for use in poultry, it was at the conclusion of the most exhaustive review process in the Center for Veterinary Medicine's history. The effort to withdraw the drug has not been subject to the same level of scrutiny.

The National Turkey Federation joins with the many others in industry and in Congress and urges you to set aside the administrative law judge's initial decision and convene a panel of experts in microbiology, epidemiology, food safety, and risk assessment. This review panel can give the scientific evidence the thorough review it deserves and make a truly objective decision on the continued use of fluoroquinolones in poultry.

We appreciate your consideration of this request, and we look forward to your response.

Sincerely,



Harley B. Sietsema