



# CONGRESS OF THE UNITED STATES

September 1, 2004

**TOM LATHAM**  
Congressman  
4th District, Iowa

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

Dear Dr. Crawford:

I am writing to express concern with the process FDA's Center for Veterinary Medicine (CVM) is proposing to withdraw approval for the use of a fluoroquinolone (enrofloxacin) in poultry. I completely support FDA's public-health mission, but I also believe that the long-term consequences of banning fluoroquinolone requires scientific certainty.

According to information I have received, the agency approved fluoroquinolone for use in poultry in 1996 after one of the most exhaustive animal drug reviews in CVM's history. Safeguards were put in place to ensure the drug's safe, effective use and to monitor potential increases in antibiotic resistance among animals and humans. Additional protections were added in 1997, when CVM banned "extra-label" use of fluoroquinolones. As a result of these safeguards -- and the high cost of the drugs -- fluoroquinolones are among the most sparingly used animal drugs in this country; less than 2 percent of all chickens and only about 4 percent of all turkeys are treated with the drug. This does not, however, discount the importance and efficacy of the drug.

In 2000, CVM began to move toward banning fluoroquinolone use in poultry. After a lengthy hearing, an FDA Administrative Law Judge's Initial Decision this March ruled in favor of CVM and against the manufacturer of the only remaining fluoroquinolone product on the market. The manufacturer and CVM have filed exceptions to the judge's findings, and both parties will respond to those exceptions by mid July.

Given what I have learned, I believe that the correct course of FDA action is to continue the use of fluoroquinolone's in poultry. The evidence suggests that the Administrative Law Judge could have arrived at his decision based on erroneous findings on such key matters as the probability 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.

Additionally, the decision by the judge indicates that the approval for fluoroquinolone use in turkeys may be withdrawn based on studies that were conducted almost exclusively on chickens. The judge used this data to rule the effect of fluoroquinolone use was the same on both species. CVM long has held that no drug for turkeys may be approved based solely on data from chickens, or vice versa. CVM presented no data on turkeys at the time it moved to ban fluoroquinolone use in poultry and presented only scant evidence relating to turkeys during the hearing process. I urge you to convene a panel of experts in the fields of microbiology, epidemiology, food safety and risk assessment to discuss future action.

**Washington Office:**  
440 Cannon Building  
Washington, DC 20515  
202-225-5476  
202-225-3301 Fax

**Ames Office:**  
213 North Duff Avenue, Suite 1  
Ames, Iowa 50010  
515-232-2885  
515-232-2844 Fax

**Clear Lake/Mason City Office:**  
812 Hwy 18 East  
P.O. Box 532  
Clear Lake, Iowa 50428  
641-357-5225  
641-357-5226 Fax

**Fort Dodge Office:**  
1426 Central Avenue, Suite A  
Fort Dodge, Iowa 50501  
515-573-2738  
515-576-7141 Fax

**Email:** tom.latham@mail.house.gov  
**Internet:** www.house.gov/latham

2004-4977

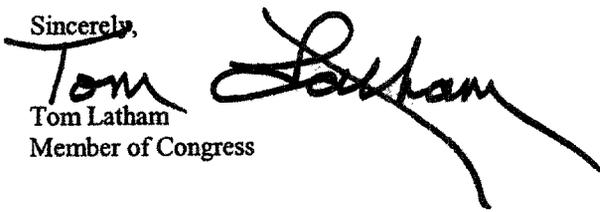
2000N-1571

C 299

Page Two  
Dr. Lester Crawford  
September 1, 2004

Again, I completely support the FDA's mission and its methods. I do, however, also believe that the continued use of fluoroquinolone's in poultry and turkeys is an issue that deserves further research as the existing evidence is insufficient to justify the drug's removal.

Sincerely,

  
Tom Latham  
Member of Congress