



APR 19 2005

Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

**MEMORANDUM**

**Date:** April 19, 2005  
**To:** Docket No. 00N-1571 (Enrofloxacin for Poultry)  
**From:** Counsel for the Commissioner,  
Office of the Chief Counsel

Pursuant to 21 CFR 10.55(d)(3), the attached documents are being provided by the Office of the Commissioner of the Food and Drug Administration (FDA) to Docket 00N-1571 to all participants.

The attached document is a letter addressed to Dr. Crawford, Acting Commissioner, regarding the Initial Decision in this matter and the response.

2000N-1571

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# 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.

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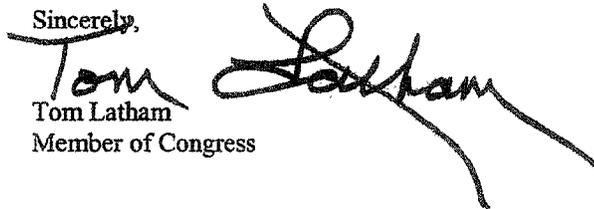
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Dr. Lester Crawford  
September 1, 2004

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,

A handwritten signature in black ink that reads "Tom Latham". The signature is written in a cursive style with a long, sweeping tail that extends to the right.

Tom Latham  
Member of Congress



The Honorable Tom Latham  
House of Representatives  
Washington, D.C. 20515-1504

MAR 15 2005

Dear Mr. Latham:

Thank you for the letter of September 1, 2004, addressed to Lester M. Crawford, Ph.D., D.V.M., Acting Commissioner of Food and Drugs, regarding the withdrawal of approval for enrofloxacin.

Under longstanding Food and Drug Administration (FDA) regulations governing the withdrawal of approval of a new animal drug, communications about this withdrawal currently are not allowed between the Commissioner and officials advising the Office of the Commissioner and persons outside FDA. (See Title 21, Code of Federal Regulations [CFR] §10.55(d)(1).) Thus, the Commissioner is unable to respond to the specific issues regarding enrofloxacin that you raised in your letter. However, we are able to provide the following information on the regulatory process for formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. In addition, under these regulations, a copy of this correspondence and this response must be placed in FDA's docket and served on the participants (21 CFR 10.55(d)(3)).

An Administrative Law Judge (ALJ) under regulations found at 21 CFR Part 12 conducts FDA's formal hearings. These regulations reflect provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act and the Administrative Procedures Act that apply to formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of new animal drug approval (NADA) 140-828, pursuant to section 512(e)(1)(B) of the FD&C Act. CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register* on October 31, 2000. Bayer filed a request for a hearing on November 29, 2000, and the Commissioner of FDA agreed, publishing a notice of hearing on February 20, 2002. Subsequently, joint stipulations and revised joint stipulations were submitted on September 20 and December 24, 2002, respectively. Documentary evidence and written direct testimony was submitted by CVM on December 9, 2002, and by Bayer and the Animal Health Institute (AHI) on December 13, 2002. Oral hearing for cross-examination of witnesses was held between April 28 and May 27, 2003. Briefs were filed on July 18, 2003, and reply briefs on August 15, 2003. The initial decision of the ALJ was issued on March 16, 2004, and the parties filed exceptions to the initial decision on May 17, 2004. On July 16, 2004, CVM filed its reply to the Bayer and AHI exceptions, and Bayer and AHI filed their reply to CVM's exceptions.

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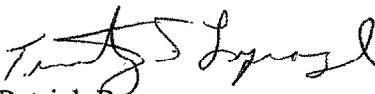
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A public docket (00N-1571) was established at the time the NOOH was published in October 2000. Documents related to the hearing, including the NOOH, referenced scientific studies, correspondence, briefs, the initial decision of the ALJ, and subsequent filings by CVM and Bayer and AHI can be found in the public docket.

Thank you again for contacting us about this matter. We hope this information is helpful. If you have further questions, please let us know.

Sincerely,

  
Patrick Ronan  
Assistant Commissioner  
for Legislation

cc: Food and Drug Administration  
Division of Dockets Management  
(Docket No. 00N-1571)  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Docket No. 00N-1571

**CERTIFICATE OF SERVICE**

I hereby certify that two copies of the foregoing Memorandum and attachment were hand delivered on April 19, 2005, to:

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

I also certify that a copy of the Memorandum and attachment were hand delivered to on April 19, 2005, to:

Claudia Zuckerman (GCF-1)  
Food and Drug Administration  
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Rockville, MD 20857

I also certify that a copy of the Memorandum and attachment were sent by U.S. mail, postage prepaid, April 19, 2005, to:

Robert B. Nicholas  
McDermott, Will & Emery  
600 13th St., NW  
Washington, DC 20005

and

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Certificate of Service (12/1/04)  
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Kent D. McClure  
Animal Health Institute  
1325 G St., NW, Suite 700  
Washington, DC 20005

DATED: 4/19/05

  
\_\_\_\_\_  
Leslie Kux (GCF-1)  
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