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August 3, 2004

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

Dear Dr. Crawford:

I am writing to you to ask you to oppose the recent rule of FDA's Administrative Law Judge Davidson in regards to the ban of enrofloxacin, (Baytril®), the only fluoroquinolone approved for the treatment of various bacterial infections in poultry.

I have been involved in poultry medicine since the beginning of my career in 1964. I hold a Doctor of Veterinary Medicine degree, a Master of Science degree, and a Ph. D. in Avian Medicine. Currently I am employed by Cornell University and I am responsible for providing technical service support to poultry producers in New York State. First of all and of extreme concern, judge Davidson ignored all the scientific evidence presented during the open hearing by Bayer's expert witness that clearly showed through a quantitative risk assessment that the potential contribution of Baytril® use in poultry to antibiotic resistance in human campylobacteriosis is negligible.

Secondly, the data collected by both, USDA and CDC through the National Antibiotic Resistance Monitoring System clearly shows that there is no correlation between antibiotic resistance patterns or trends in human and poultry isolates of *Campylobacter spp.*

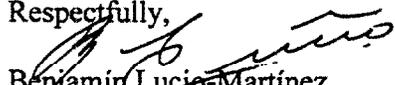
Thirdly, enrofloxacin, Baytril®, is only used in poultry when bacterial isolation and antibiotic sensitivity testing shows that it is the only effective treatment. Baytril® can only be used by prescription by a licensed poultry veterinarian with strict adherence to withdrawal requirements. Records must be kept for a number of years in all cases where Baytril® has been prescribed. All of these requirements in addition to the high cost of this medication compared to others aid in ensuring that this drug is only used very judiciously, basically only when nothing else works, and for the purpose of relieving animal suffering and catastrophic losses to poultry producers. I believe that not more than 1% of all chickens produced in the United States every year get treated with Baytril®, and even in turkeys, which have a much longer production life and are more commonly afflicted by bacterial infections, I believe that Baytril® is used in less than 5% of all the turkeys produced each year in the United States. However, in cases of systemic bacterial infections that do not respond to other drugs it is critically important to have a therapeutic alternative like Baytril®.

The fear of antibiotic resistance transmission from animals to people via the food chain has been overplayed and sensationalized by the media and the activist groups opposed to antibiotic use in food-producing animals. Realistically speaking society would be much

better served if agencies like FDA, CDC and USDA spend more time and resources educating people and restaurant owners about the importance of good hygiene habits in the kitchen and on adequate cooking temperatures. Dead bacteria can not transmit antibiotic resistance so any illness-causing bacteria acquired by eating food indicates a lack of proper hygiene in the kitchen, or consumption of food that has been improperly stored or cooked.

I have always been encouraged and proud of FDA's position in letting the science prevail over the politics and the personal agendas. I hope that the final ruling on the future availability of Baytril® to the poultry industry will be based on conclusive scientific evidence and quantitative risk assessments continuing on with a long tradition of science and fairness.

Respectfully,

  
Benjamin Lucio-Martinez  
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CC: Dockets Management Branch, ref. # 00N-1571



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

September 29, 2004

Benjamin Lucio-Martinez, D.V.M., M.S., Ph.D.  
Poultry Diagnostic and Extension Services  
NYS Animal Health Diagnostic Laboratory  
C4-121 Veterinary Medical Center, Box 5  
College of Veterinary Medicine, Cornell University  
Ithaca, New York 14853

Dear Dr. Lucio-Martinez:

Thank you for your letter of August 3 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.

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The parties and AHI filed post-hearing briefs and replies in the summer of 2003 and the 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,



LaKiana D. Caldwell

Director

Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)