CARROLL'S TURKEYS LLC
P. O. Drawer 856
WARSAW, NORTH CAROLINA 28398

September 17, 2004

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

Dear Dr. Crawford:

My name is Shannon Jennings. I have been the corporate veterinarian for Carroll's Turkeys LLC for 17 years. I have a BS and Masters from Clemson University and earned my Doctor of Veterinary Medicine from the University of Georgia, and I am Board Certified by the College of Poultry Veterinarians.

I am writing you with regards to the Fluoroquinolone (Baytril) issue being considered by your office. I am concerned that if the industry loses Baytril we will be losing a unique antibiotic used to fight severe cases of E. coli or Fowl Cholera (Pasturella multocida) infections.

Preventing diseases in our flocks is my goal, but despite best efforts and good management, diseases will still occur.

I have had to use Baytril from time to time to treat severe infections in our turkey flocks. I have never seen an antibiotic work as well as Baytril to reduce disease and animal suffering. I am only talking about 3-4% of the flocks, but it is the drug of last resort. Prior to Baytril being introduced on the market, I have seen on several instances a virulent strain of Fowl Cholera kill a whole house of turkeys in 5 days despite the antibiotics available at the time. I prescribed Baytril on this same scenario two years ago, and it stopped the dying and brought the mortality back to normal levels in 4 days. This disease without Baytril could easily put our turkey farmers out of business if you withdraw it from the market.

It is my understanding that the work done on risk assessment to human health pertaining to Baytril. use was done on chicken and not turkey. Having worked with both species my entire professional career, there are tremendous differences in the resident intestinal bacterial populations, conditions in which each is grown, methods of processing and how final products are marketed to the public.

This also would set a precedent for the removal of other antibiotics based more on emotions rather than science. I would urge you to appoint an independent panel of scientific experts, to include poultry veterinarians, to review all the information pertaining to the human health risks from the way Baytril is currently used. Once a true scientific review is done I believe it will **not** support the removal of enrofloxacin (Baytril) in poultry.

Sincerely,

R. Shannon Jennings, DVM, ACPV
Corporate Veterinarian
Carrolls Turkey's, LLC

CC: Dockets Management Branch, ref. # 00N-1571
Senator Elizabeth Dole
Senator John Edwards
Congressman Richard Burr
Congressman Bob Etheridge
Congressman Robin Hayes
Congressman Walter B. Jones
Congressman Mike McIntyre

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

R. Shannon Jennings, D.V.M., A.C.P.V.
Corporate Veterinarian
Carroll's Turkeys, LLC
P.O. Drawer 856
Warsaw, North Carolina 28398

Dear Dr. Jennings:

Thank you for your letter of September 17 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

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

LaJuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)