October 28, 2004

Dr. Lester Crawford
Acting Director
Food and Drug Administration
5600 Fishers Lane, Room 1471
Mail Stop HF-1
Rockville, Maryland 20857

Dear Dr. Crawford:

This letter is my belated response to the ongoing uncertainty of Baytril's use in poultry. I am a board certified poultry veterinarian employed by one of the larger poultry integrators in the United States. I have obvious professional interest in maintaining efficacious therapies for my patients, but I also have personal human health concerns as a father of five small children. I do not want to violate my veterinary oath by suffering animals unnecessarily, and I do not want to put my children at risk of any untreatable bacterial infection.

With this being said, I have tried to stay abreast of the proceedings concerning Baytril's use in poultry. It appears to me that scientific facts are being overlooked in favor of some activists' agenda. The decision to remove Baytril at this time would demonstrate the power of political action over science. One truly efficacious intervention would be removed from veterinary care for poultry without any benefit to human health. In fact, more people may be at risk of bacterial contamination from unsuccessfully treated sick animals. I feel that my children are at greater risk of over-prescribed human antibiotics without diagnostic work-up than they are from the responsible use of antibiotics in poultry veterinary medicine.

I ask that you consider the science supporting the continued use of Baytril as a therapeutic antibiotic in poultry and urge you to overturn Judge Davidson's ruling until further review.

Thank you for your consideration.

Sincerely,

Philip A. Stayer, DVM, MS, ACPV
Corporate Veterinarian
Sanderson Farms, Inc.
P.O. Box 988
Laurel, MS 39441-0998d

cc: Dockets Management Branch, ref# 00N-1571

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 8, 2004

Philip A. Stayer, D.V.M., M.S., A.C.P.V.
Corporate Veterinarian
Sanderson Farms, Inc.
P.O. Box 988
Laurel, Mississippi 39441-0988d

Dear Dr. Stayer:

Thank you for your letter of October 28 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
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)