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October 20, 2004

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

Dear Dr. Crawford:

Please consider setting aside the Initial Decision by the Administrative Law Judge recommending the withdrawal of the NADA for Baytril (enrofloxacin), or appointing a select panel including practicing poultry veterinarians or other experts qualified in poultry practice, such as a diplomates of the American College of Poultry Veterinarians, or active members of the American Association of Avian Pathologists, to review this matter and make a recommendation.

I am the senior production veterinarian for Goldsboro Milling Company. In that capacity, I administer health programs for over 9 million market turkeys and 250,000 turkey breeders annually and have done so for over 18 years, with dotted line responsibilities into our 70,000 sow and 1200 head brood cow divisions. I am a second-generation turkey producer; my academic credentials include a DVM (ISU'74), a MS (University of Minnesota '76, major – avian microbiology, minor – biometry) and a PhD (NCSU '91, major - veterinary pathology, minor-poultry science). I am certified in poultry production and management by the American Registry of Professional Animal Scientists and am a diplomate of the American College of Poultry Veterinarians with a term on the Board of Governors. I have served as the National Turkey Federation (NTF) liaison to the AVMA Steering Committee on Antibiotic Resistance, and helped prepare the Judicious Use Guidelines for Poultry. I am an adjunct associate professor with the Population Health & Pathobiology Department at North Carolina State University, and serve NTF on the Live Production Committee. I hold memberships and usually committee assignments with the American Veterinary Medical Association, the American Association of Avian Pathologists, the Poultry Science Association, the US Animal Health Association, the American Association of Food Hygiene Veterinarians, the Association of Veterinarians in Turkey Production, and the American Association of Swine Veterinarians. I am licensed to practice veterinary medicine in North Carolina.

I have followed CDC and PHS opinion-making on fluoroquinolone use in poultry for years, and contacted Bayer and AHI to volunteer as an expert witness on their behalf as soon as it became apparent that input from clinical poultry practice was needed.

I will not reiterate my testimony or comments to the Docket , or my original comments on the NOOH although you may find them informative –a search of the FDA website under my name will produce them – if not, I will be happy to furnish copies.

My original testimony submitted to the ALJ prior to the motions to strike might also be informative. Of course, I believe my testimony should have remained intact, in part because an entire section was removed because I did not explain why I chose the dates I did for the data presented. I didn't understand this would be an issue – the dates chosen were 5 years of data ending just prior to the NOOH. Another section was removed due to a perceived grammatical error – I used the words "may be" instead of "have been and will in the future be". The ALJ apparently believed I was posing a hypothetical situation rather than one that had actually occurred and would continue to occur. In several other instances, the ALJ seemed to have difficulty distinguishing between my professional opinion, my personal knowledge, referenced facts, and areas where I have personal expert experience. Consequently I believe substancial portions of my testimony were stricken in error if I understand the intent of OR31. Indeed, I am not sure the ALJ understood in what areas a senior poultry clinician with my training is expert.

I was particularly startled by the ALJ's assertion that "Nevertheless, there are in fact effective alternatives to enrofloxacin including chlortetracycline, oxytetracycline, sulfomyxin, and tetracycline". The ALJ completely set aside the opinion of every single poultry clinician testifying - that there are no current therapeutic replacements for enrofloxacin. Setting aside that clinical experience, which is vastly greater than that of the ALJ or CVM staff, seems peculiar at best. On pharmacological grounds alone I find the assertion that a bacteriostatic antibiotic is a functional replacement for a bacteriocidal antibiotic in the face of a gram-negative bacteremia associated with either colibacillosis or fowl cholera to be extraordinarily uninformed. I have also been completely unable to find any form of sulfomyxin suitable for use in poultry and would appreciate any guidance you could provide on its availability for drinking water use. I am unable to locate a source.

I am convinced the exhibits and testimony in this matter have not been impartially reviewed by knowledgeable authority. I urge you to consider either setting this opinion aside, or convening a panel of informed, impartial experts to render a recommendation that considers all the information available. The well-being of my patients is an issue that I believe should be treated with some degree of gravitas by knowledgeable authority.

Sincerely,

Eric Gonder, DVM, MS, PhD, PAS, ACPV

cc: Food and Drug Administration, Dockets Management Branch
Dr. Lyle Vogel, NTF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 29, 2004

Eric Gonder, D.V.M., M.S., Ph.D., P.A.S., A.C.P.V.
Goldsboro Milling Company
938 Millers Chapel Road
Post Office Box 10009
Goldsboro, North Carolina 27532

Dear Dr. Gonder:

Thank you for your letter of October 20 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)