



CARROLL'S TURKEYS LLC

P. O. Drawer 856
WARSAW, NORTH CAROLINA 28398

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

Dear Dr. Crawford,

My name is Keith Shoemaker. I am currently President of Carroll's Turkeys with Murphy-Brown LLC in Warsaw, NC a division of Smithfield Foods. Additionally, I have worked for many years in the chicken industry as Vice President of Operations with Perdue Farms. My career in management in the poultry business spans over 20 years.

I write to express great concern regarding the process by which the Center for Veterinary Medicine (CVM) and the recent ALJ Initial Decision appear to be evaluating the evidence in the NOH proceeding to remove Baytril from the market in chickens and turkeys. Overall, I am concerned that CVM is attempting to "throw the baby out with the bath water" and may be making a substantial error relative to the best action for protecting public health as well as serving animal agriculture responsibly. This is especially true regarding issues specific to the turkey industry.

It is my understanding that the final decision on this matter will rest entirely in your hands. I therefore ask you to consider some important points in your review of this matter.

Firstly, we have no alternatives to Baytril. There are no products on the market that perform anywhere close to Baytril for reducing mortality in flocks with serious infections. In many cases we will simply have to stand by and watch animals die if Baytril is no longer available.

Secondly, since HACCP regulations were signed into law via the President's Food Safety Initiative in 1996 and implemented in large processing plants in 1997

poultry products have shown consistent improvements for generic E. coli and Salmonella prevalence. I am confident that this improvement applies to processed turkey as well as chicken products. Why then is CVM attempting to implicate poultry as an increasing risk of food borne disease?

Thirdly, although I am not familiar with all the evidence, I am aware that there is little or no evidence that demonstrates any risk of food borne disease coming from turkey meat. In such a circumstance it is incredible to me that CVM would attempt to remove such an effective product from the market.

Lastly, healthy animals produce safer food. CVM's current line of thinking seems to be that sending sick animals to processing will have no impact on the safety of the resulting food produced. I can absolutely assure you that this will not be the case. Sick animals challenge the processing system substantially and healthy animals allow it run very smoothly.

It's appears time for your office and oversight to inject some sound judgment into this process. I urge you to review this issue carefully and objectively as it has important ramifications for animal agriculture's future here in the United States. Use seasoned experts who can give this topic a fair day in court.

Thank you in advance for your consideration in this matter.

Respectfully Submitted,



Keith Shoemaker

Cc: Docket # 00N-1571



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

Keith Shoemaker
President
Carroll's Turkey LLC
P.O. Drawer 856
Warsaw, North Carolina 28398

Dear Mr. Shoemaker:

Thank you for your letter 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

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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,

A handwritten signature in cursive script, appearing to read "LaJuana D. Caldwell".

LaJuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)