

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

8/9/04

Dear Dr. Crawford,

I am writing on behalf of the Drugs and Therapeutics Committee of the American Association of Avian Pathologists (AAAP). We are deeply alarmed about the recent ruling by FDA Judge Davidson to support withdrawal of Baytril claims for use in poultry. This is a rather perplexing conclusion to us in that we felt the arguments presented by Bayer were strong, rational evidences that Baytril is not the threat to human health as it has been portrayed. To be frank, it seems that much of Bayer's evidence was ignored or dismissed without regard to sincere consideration. There simply is not enough scientific evidence to pull Baytril from the market at this time, and until such time, we should not be relying upon suppositions or faulty risk assessments to do so.

To the point, there is simply not another approved therapeutic antibiotic with the efficacy of Baytril against colibacillosis infections in poultry. We don't treat the vast majority of flocks placed, but when we do, we need a product that works to improve the health/welfare of the flock and to prevent suffering. Some uninformed individuals may believe that we have equally efficacious alternatives, but I can assure you, there is not a better treatment. We do not use this product indiscriminately due to expense and ethics, and the poultry industry will do the right thing if there is credible data to suggest otherwise, but we do not want to lose Baytril because of perceived "fear factors".

Our committee is primarily made up of poultry production veterinarians, technical services veterinarians, and university professors. I understand that you are planning to assemble a team of experts to review this matter. As there are literally decades of practical experience and expertise to draw from within this committee and the AAAP, I would urge you to consider placing an individual(s) with real world working knowledge of the poultry industry from our organization on this panel. This is too important an issue to both poultry and human health to have wrong associations made. Thank you for your time and consideration, and I would appreciate a response if possible.

Sincerely,



Timothy S. Cummings, DVM, MS, ACPV  
Chair of the Drugs & Therapeutic Committee  
Clinical Poultry Professor  
P.O. Box 6100  
College of Veterinary Medicine  
Mississippi State, MS 39762  
Phone: 662-325-1113  
Email: [cummings@cvm.msstate.edu](mailto:cummings@cvm.msstate.edu)

2000N-1571

C 272

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

Committee Members:

Dr. Hector Cervantes: Phibro Animal Health

Dr. Steve Clark, Alpharma

Dr. Rafeal Fernandez, Merial

Dr. Eric Gonder, Goldsboro Milling

Dr. Tom Holder, Allen's Family Foods

Dr. Dan Karunakaran, Cargill

Dr. Barry Kelly, Bayer

Dr. Buzz Klopp, Townsends Inc.

Dr. Beth Krushinskie, Pilgrim's Pride Corp.

Dr. Bret Rings, Tyson Foods

Dr. John Smith, Fieldale Farms

Dr. Robert Williams, Keystone Foods

Dr. Susan Young, University of Georgia