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8876 '00 FEB 14 A9:53

February 7, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket Number 98D-0969**

To Whom It May Concern:

I am writing in regards to the proposed "Risk Assessment on the Human Health Impact of Fluoroquinilone Resistant Campylobacter Associated with the Consumption of Chicken" being developed by CVM/FDA. I have read the letter jointly submitted by The National Chicken Council and Association of Veterinarians in Broiler Production and am in full support of that document. Several points that I think should be emphasized are;

The risk assessment does NOT evaluate the development of resistance to fluoroquinilones as a consequence of treatment of chickens with that drug. The model assumes that all chickens are treated with fluoroquinilone which is not the case. FDA/CVM is well aware that a very small percentage of poultry flocks are treated with fluoroquinilones. Along that line, no data are available to determine the level of innate resistance in Campylobacter as no sensitivity testing was conducted prior to introduction of the drugs to the poultry industry in 1995.

While research is in progress, no one currently knows the epidemiology of Campylobacter, much less the method of transmission to poultry. This is a critical fact to understand when trying to learn how the bacterium develops resistance to any antimicrobial drug, including fluoroquinilones.

In the isolation and testing procedures used in the laboratory, nalidixic acid is used as a screening method to eliminate other species of Campylobacter from testing. Such a procedure appears to bias the resistance profile as nalidixic acid resistance is considered by many to be a precursor to development of resistance to fluoroquinilones.

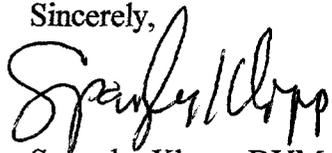
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While I recognize that decisions must often be made before facts are completely understood scientifically, my overall concern with the risk assessment is that science is not even being used to direct the philosophy of development and usage of antibacterial drugs in food producing animals. Rather it appears that facts and statements are being manipulated to a predetermine end result- ie – all resistant bacteria come from usage of antibacterial drugs in food producing animals.

Thank you for taking time to read and evaluate my letter and if I can be of further assistance please contact me.

Sincerely,

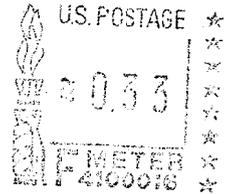
A handwritten signature in black ink, appearing to read "Spangler/Klopp". The signature is written in a cursive, flowing style.

Spangler Klopp, DVM, Dpl ACPV  
Corporate Veterinarian

Gen/fqcvm200



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