DELMARVA POULTRY INDUSTRY, INC.
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March 2, 2000

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

Re: Docket Number 98D-0969

We are writing on behalf of Delmarva Poultry Industry, Inc. (DPI), the trade association for the broiler chicken industry in Delaware, Maryland, and the Eastern Shore of Virginia.

Shown below are DPI's comments on the proposed "Risk Assessment on the Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken" being developed by CVM/FDA. We are in full support of the letter submitted by The National Chicken Council and Association of Veterinarians in Broiler Production. Several points need to be emphasized.

The risk assessment does NOT evaluate the development of resistance to fluoroquinolones as a consequence of chickens being treated with that drug. The model assumes that all chickens are treated with fluoroquinolone, which is not the case. FDA/CVM is well aware that a very small percentage of poultry flocks are treated with fluoroquinolones. 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 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 fluoroquinolones.

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 fluoroquinolones.

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While we understand that decisions often must be made before facts are completely understood scientifically, our 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 predetermined end result- i.e. – all resistant bacteria come from usage of antibacterial drugs in food producing animals.

Thank you for considering DPI's comments on this matter.

Sincerely,

Spangler Klopp

Spangler Klopp, DVM, Dpl ACPV
Chairman, DPI Poultry Health Committee

Bill Satterfield

Bill Satterfield
Executive Director

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