fieldale farms corporation

February 9, 2000

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

RE: Docket Number 98D-0969

Dear Sir/Madam:

I am a practicing veterinarian employed by Fieldale Farms Corporation, a privately held producer of broiler chickens in Georgia. We produce approximately 3.2 million broilers per week. I wish to comment on the Center for Veterinary Medicine's draft risk assessment model, Docket Number 98D-0969.

As a practitioner, I am obviously interested in preserving my access to fluoroquinolones if possible. However, I am most interested in the truth. If the use of these drugs in poultry indeed poses a significant risk to consumers, then their use should be discontinued. Neither I nor any of my colleagues want to be a party to injuries to human health. We are not only managers of poultry health, but also are part of a team protecting public health. However, if the risk is negligible and is outweighed by potential benefits, the drugs should remain available. The benefits are considerable. These drugs are economically important not only to the poultry producing companies, but also to the independent contract growers and the consumer. We feel that they help us produce a more wholesome, quality product. We have no comparable products to replace these drugs. Finally, these compounds are being used responsibility. My colleagues and I are aware of the potential implications of the use of fluoroquinolones. Moreover, even if we disregarded those implications, the extreme cost of these drugs forces us to be very judicious in their application.

A reasonable, reliable model is needed to objectively assess the impact of fluoroquinolone use in food animals on human health, and to provide a science-based answer to this issue. A number of assumptions in the present model raise serious questions as to whether this model will provide that objective, scientific answer. A few are cited here as examples.

Pre-existing clones of *Campylobacter* with naturally - occurring resistance to fluoroquinolones (FQ) undoubtedly existed prior to the introduction of these drugs. If any data exists to suggest the incidence of this pre-existing, innate resistance, it is not utilized in the model. Without

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knowledge of the pre-existing level of resistance, it is impossible to estimate how much of the present level of resistance is attributable to FQ use in food animals.

The assumptions that essentially all of the *Campylobacter* infections in humans arise from poultry and that all of the FQ resistance in these organisms is due to FQ use in poultry, are erroneous for several other reasons. Dairy products, red meat, produce, drinking water, companion animals, and occupational exposures are possible sources of *Campylobacter* infections. The use of FQ antibiotics in humans and companion animals surely has some role in the induction of resistance in *Campylobacter.*

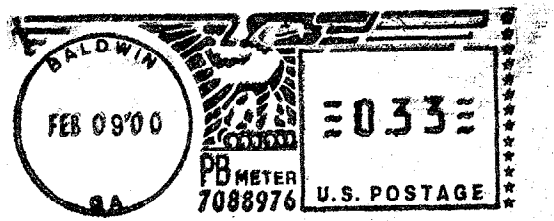
If I understand the model correctly, it appears that the argument is made that, as the severity of symptoms increase (and increasing levels of medical care are sought), the probability that the causative organism is FQ - resistant increases dramatically. Has this been documented to occur? Unless virulence and resistance to FQ are closely linked in some manner, it would seem more likely that the incidence of FQ resistance in mild and severe clinical cases should be similar.

In summary, I believe that an objective, science-based assessment of the use of these and other antibiotics in food animals is needed. This debate needs the true answers. I am very concerned that the proposed model contains numerous unfounded assumptions that will not permit the model to provide that true, objective, scientific, and unbiased answer.

Sincerely,

John A. Smith, DVM, MS, MAM
Diplomate, ACVIM, ACPV
Director of Health and Hatchery Services

JAS/nw



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