



09-15-04P01:49 RCVD

August 13, 2004

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

Dear Dr. Crawford:

Jennie-O Turkey Store is the largest integrated turkey production company in the world, processing 200,000 turkeys per day. Our live production facilities are located in Wisconsin and Minnesota, and we have a large group of contract producers located throughout Minnesota and bordering states. We are very concerned about FDA's proposed withdrawal of the approval to treat turkeys with enrofloxacin without a fair evaluation of the science and risk involved.

Our production facilities are located in a region of the country where turkey respiratory diseases are our greatest challenge. Our staff veterinarians have made great progress over the years in the prevention of respiratory disease outbreaks. However, field virus challenges sometimes result in secondary *E. coli* infections that can cause high mortality and morbidity. Contrary to the opinion of the administrative law judge, we have no alternative to enrofloxacin for the effective treatment of severe *E. coli* infections. Our veterinarians use enrofloxacin only in severe cases where no other antibiotic will be effective.

Jennie-O Turkey Store veterinarians have reviewed some of the evidence presented in the hearing on the proposed withdrawal of approval and the administrative law judge's ruling. Interpretation of key issues involved, including the risk of transfer of *Campylobacter* infections to humans, the methods used to define resistance, and the incidence of resistance in humans, are questionable. Even more troubling is the effort to base the withdrawal of approval for turkeys on the data derived from chicken studies. Even if the chicken data were perfectly valid, extrapolation to turkeys is absurd. A turkey is not a "big chicken." FDA has not allowed the approval of any drug in turkeys based on chicken data, so how can chicken data be used to withdraw an approval for turkeys?

Obviously, this issue has not received the scientific attention it deserves. Even in Europe, where the precautionary principle has precluded scientific review, enrofloxacin has been found to pose no threat to the public health when used judiciously in poultry. FDA has traditionally used sound science to deal with these issues. It seems politics are getting in the way. We urge the FDA to return to sound science. We join the National Turkey Federation and others in the industry and in Congress and request that you convene a panel of experts, including veterinary specialist in poultry medicine, to review the evidence scientifically, and give this important issue the scientific attention it deserves.

Jennie-O Turkey Store

34 North Seventh Street Barron, WI 54812 (715) 537-3131

2000N-1571

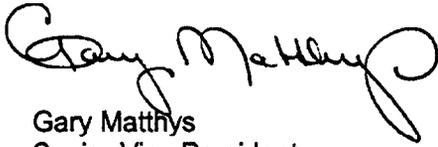
2004-4543

C 290

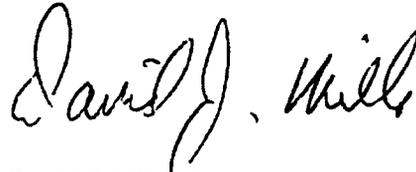
August 13, 2004
Dr. Lester Crawford
Page -2-

Your consideration of this request is greatly appreciated.

Sincerely,



Gary Matthys
Senior Vice President



David J. Mills, D.V.M.
Director, Live Production Technical Support

cc: Food and Drug Administration
Dockets Management Branch
Ref. Docket # 00N-1571
5630 Fishers Lane
Room 1061
Rockville, MD 20857