



09-15-04 P01:49 PCVD

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

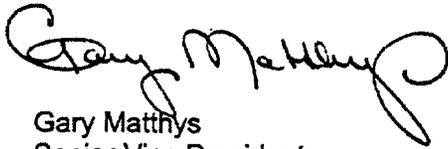
34 North Seventh Street Barron, WI 54812 (715) 537-3131

2004-4543

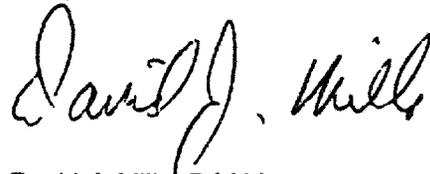
August 13, 2004
Dr. Lester Crawford
Page -2-

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

David J. Mills, D.V.M.
Director
Live Production Technical Support
Jennie-O Turkey Store
34 North Seventh Street
Barron, Wisconsin 54812

Dear Dr. Mills:

Thank you for your letter of August 13, co-signed by Mr. Gary Matthys, addressed to Dr. Crawford regarding the proposed withdrawal of the approval of enrofloxacin use in poultry. As described below, this matter is now pending before Dr. Crawford.

Under longstanding federal regulations governing the withdrawal of approval of a new animal drug, communications about this proposed withdrawal are not allowed between the Commissioner, officials advising the Office of the Commissioner, and persons outside the Food and Drug Administration (FDA). See Title 21 Code of Federal Regulations, Section 10.55(d)(1) (21 CFR 10.55 (d)(1)). Therefore, Dr. Crawford is unable to respond to the specific issues regarding enrofloxacin that you raise in your letter. For your information, under these regulations, a copy of your correspondence and this response must be placed in the FDA docket and served on the participants. See 21 CFR 10.55(d)(3).

However, I am able to provide the following information on the regulatory process for FDA's formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. The FDA's formal hearings are conducted by an administrative law judge under regulations found at 21 CFR part 12. These regulations set out the procedures that FDA must follow when conducting formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of the New Animal Drug Application (NADA) 140-828, pursuant to Section 512(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act. That section requires that a new animal drug must be shown to be safe and effective for its intended uses. On October 31, 2000, CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register*. On November 29, 2000, Bayer filed a request for a hearing. The FDA Commissioner agreed and published a Notice of Hearing on February 20, 2002, in the *Federal Register*.

After submission of documentary evidence, written direct testimony, and joint stipulations by CVM, Bayer Corporation, the sponsor of the animal drug, and non-party participant Animal Health Institute (AHI), an oral hearing for cross-examination of witnesses was held between April 28 and May 7, 2003, with Administrative Law Judge Daniel J. Davidson presiding.

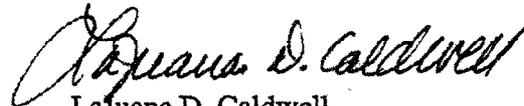
Page 2 – Dr. David J. Mills

The parties and AHI filed post-hearing briefs and replies in the summer of 2003 and the administrative law judge issued an initial decision on March 16, 2004. The parties have filed exceptions to the initial decision.

A public docket was established at the time the NOOH was published in October 2000. The record of the hearing, which includes the NOOH, referenced scientific studies, briefs, hearing transcripts, the initial decision of the administrative law judge, and subsequent filings by CVM, Bayer, and AHI, can be found in this public docket (Docket No. 2000N-1571).

I hope this information is helpful. A similar letter was sent to Mr. Gary Matthys. Thank you for your interest in this issue.

Sincerely,



Lajuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

Gary Matthys
Senior Vice President
Jennie-O Turkey Store
34 North Seventh Street
Barron, Wisconsin 54812

Dear Mr. Matthys:

Thank you for your letter of August 13, co-signed by Dr. David J. Mills, addressed to Dr. Crawford regarding the proposed withdrawal of the approval of enrofloxacin use in poultry. As described below, this matter is now pending before Dr. Crawford.

Under longstanding federal regulations governing the withdrawal of approval of a new animal drug, communications about this proposed withdrawal are not allowed between the Commissioner, officials advising the Office of the Commissioner, and persons outside the Food and Drug Administration (FDA). See Title 21 Code of Federal Regulations, Section 10.55(d)(1) (21 CFR 10.55 (d)(1)). Therefore, Dr. Crawford is unable to respond to the specific issues regarding enrofloxacin that you raise in your letter. For your information, under these regulations, a copy of your correspondence and this response must be placed in the FDA docket and served on the participants. See 21 CFR 10.55(d)(3).

However, I am able to provide the following information on the regulatory process for FDA's formal evidentiary hearings and a brief outline of selected milestones in the case of enrofloxacin. The FDA's formal hearings are conducted by an administrative law judge under regulations found at 21 CFR part 12. These regulations set out the procedures that FDA must follow when conducting formal hearings.

The Center for Veterinary Medicine (CVM) proposed to withdraw approval of the New Animal Drug Application (NADA) 140-828, pursuant to Section 512(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act. That section requires that a new animal drug must be shown to be safe and effective for its intended uses. On October 31, 2000, CVM published a notice of opportunity for hearing (NOOH) in the *Federal Register*. On November 29, 2000, Bayer filed a request for a hearing. The FDA Commissioner agreed and published a Notice of Hearing on February 20, 2002, in the *Federal Register*.

After submission of documentary evidence, written direct testimony, and joint stipulations by CVM, Bayer Corporation, the sponsor of the animal drug, and non-party participant Animal Health Institute (AHI), an oral hearing for cross-examination of witnesses was held between April 28 and May 7, 2003, with Administrative Law Judge Daniel J. Davidson presiding. The parties and AHI filed post-hearing briefs and replies in the summer of 2003 and the

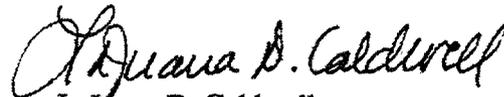
Page 2 – Mr. Gary Matthys

administrative law judge issued an initial decision on March 16, 2004. The parties have filed exceptions to the initial decision.

A public docket was established at the time the NOOH was published in October 2000. The record of the hearing, which includes the NOOH, referenced scientific studies, briefs, hearing transcripts, the initial decision of the administrative law judge, and subsequent filings by CVM, Bayer, and AHI, can be found in this public docket (Docket No. 2000N-1571).

I hope this information is helpful. A similar letter was sent to Dr. David J. Mills. Thank you for your interest in this issue.

Sincerely,



Lajuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)