

N A T I O N A L

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August 10, 2004

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

08-13-04 09:59 RCVD

Dear Dr. Crawford:

The National Turkey Federation represents all segments of the turkey industry including processors, growers, breeders, hatchery owners and allied companies. NTF is the only national trade association representing the turkey industry exclusively. Our members have worked closely with Congress and FDA over the years to create an environment in which safe, effective animal drugs can be approved in a science-based, expeditious manner. Our members are extremely concerned about the process by which FDA's Center for Veterinary Medicine (CVM) is proposing to withdraw approval for the use of a fluoroquinolone (enrofloxacin) in poultry.

Fluoroquinolones are used extremely sparingly in the turkey industry and only under the direction of licensed veterinarians – less than 5 percent of all turkeys produced in the United States ever receive fluoroquinolones. The cost of the drug and the industry's tight operating margins require our members to use this as a drug of last resort. But, when fluoroquinolones are used, they are absolutely essential for treating coli septicemia infection, a serious disease for turkeys. If our members could not administer the drug in those instances, they would suffer significant losses in their flocks; the mortality rate in flocks would increase by 200 to 300 percent. Contrary to the administrative law judge's initial decision in this case, there are not effective alternative treatments available.

NTF's members have felt this regulatory issue has been mishandled from the publication of the original Notice of Opportunity for Hearing in 2000. We believe the preponderance of evidence available then, as now, indicates fluoroquinolone use in poultry is having no impact on human health, nor is it likely ever to have an impact. Resistance data indicate the incidence in humans of campylobacteriosis decreased from 2.4 million cases to 1.4 million cases the first three years the drug was in use. More significantly, the incidence of fluoroquinolone-resistant *Campylobacter* infections in humans decreased from 3.28 to 2.62 cases per 100,000 population between 1997 and 2001. Finally, there are effective alternatives available to treat campylobacteriosis in humans, which – as we have noted – is not the case in turkey production.

In February 2001, NTF filed comments with FDA urging the agency to halt its regulatory activity against fluoroquinolones. Absent that action, we asked FDA to grant the



2004-4535

manufacturer a hearing, which FDA consented to do. We believe the evidence presented at the hearing raised serious doubts about the validity of FDA's case, and we believe the administrative law judge made several erroneous rulings in his initial decision. We believe there is sufficient evidence to indicate the judge made errors on such key matters as the likelihood of transferring resistant *Campylobacter* infections from poultry to humans, the incidence of fluoroquinolone-resistant campylobacteriosis in humans, the duration of illness for people who contract resistant campylobacteriosis and the public health benefits realized from the use of fluoroquinolones in poultry.

However, our biggest concern with the judge's initial decision is the problem we have had from the outset of this case. When FDA first proposed withdrawing approval of fluoroquinolones in poultry, it did so based strictly on studies conducted in chickens. This simply is unconscionable and directly contradicts more than 40 years of policy at the agency. FDA officials have long held that a drug could not be approved for use in turkeys based solely on data collected in chickens. The agency contended that there are too many physiological differences between the birds to treat a turkey like a "big chicken." Now, the agency is saying that its long-held position does not apply to the withdrawal of a drug. This borders on being hypocritical.

If the agency now contends it can withdraw approval for a turkey drug based strictly on chicken data, then we do not see how the agency has any legal choice but to begin approving turkey drugs based solely on chicken data.

When the agency first approved fluoroquinolones for use poultry, it was at the conclusion of the most exhaustive review process in the Center for Veterinary Medicine's history. The effort to withdraw the drug has not been subject to the same level of scrutiny.

The National Turkey Federation joins with the many others in industry and in Congress and urges you to set aside the administrative law judge's initial decision and convene a panel of experts in microbiology, epidemiology, food safety, and risk assessment. This review panel can give the scientific evidence the thorough review it deserves and make a truly objective decision on the continued use of fluoroquinolones in poultry.

We appreciate your consideration of this request, and we look forward to your response.

Sincerely,

A handwritten signature in cursive script that reads "Alice Johnson, DVM". The signature is written in black ink and is positioned above the typed name and title.

Alice Johnson, DVM
President



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

Alice Johnson, D.V.M.
President
National Turkey Federation
1225 New York Avenue, N.W.
Suite 400
Washington, D.C. 20005

Dear Dr. Johnson:

Thank you for your letter of August 10 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.

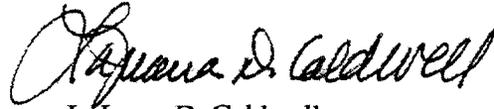
Page 2 – Dr. Alice Johnson

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. Thank you for your interest in this issue.

Sincerely,



LaJuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)