



Charles L. Hofacre, Secretary-Treasurer of AAAP
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September 2, 2004

Dr. Lester Crawford, Acting Director
Food and Drug Administration
5600 Fishers Lane, Room 1471
Mail stop HF-1
Rockville, Maryland 20857

Dear Dr. Crawford,

The American Association of Avian Pathologists (AAAP) is a member organization of the American Veterinary Medical Association (AVMA). It meets annually in conjunction with the AVMA each summer, and is currently composed of 700 members representing all areas of avian specialty relating ultimately to the diagnosis, prevention and treatment of disease. Its membership is international, composed of avian veterinary practitioners and research scientists from diverse employment backgrounds: University faculty and research staff, state diagnostic laboratories, national research laboratories (USDA, FSIS, ARS), National Poultry Improvement Plan (NPIP), the broiler and turkey production industry, allied industries, and minor species industries (ducks, quail, etc.). The AAAP has many committees that give guidance and formulate positions for the AVMA on avian-specific issues (i.e., Animal Welfare Guidelines, Food Safety, Judicious Use of Antimicrobials), as well as formulating disease control policies for the AAAP (i.e., Avian influenza, Exotic Newcastle Disease control). The AAAP is governed by a Board of Directors that will, on occasion, and at the direction of the membership by vote, state the views of the organization on matters of a serious nature that impact the potential health of the National Poultry Flock.

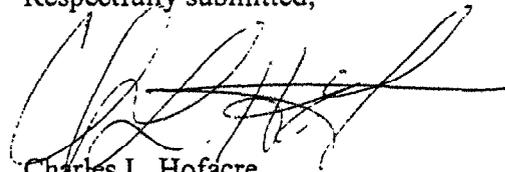
As Secretary-Treasurer of the AAAP, I have been instructed by the Board of Directors to inform you of the concerns of the AAAP membership regarding the process of the NOH for Baytril (enrofloxacin), Docket #00N-1571, and the on-going review of the administrative law judge's Initial Decision. We have followed closely the scientific arguments as well as the legal ones since the NOOH was issued, and believe that Judge Davidson's ruling was not science-based, did not have a solid legal foundation, and inappropriately struck or ignored critical testimony by

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expert witnesses, many of whom are AAAP members of high regard, including at least 2 past presidents. We believe that evidence presented during the NOB proceedings demonstrates that a healthy National Poultry Flock is essential to a safe food supply, that there are no effective available alternatives to enrofloxacin, and that the benefits derived from its use far out-weigh the risks. We consider the availability of enrofloxacin to be essential to the control of *E. coli* infections in chickens and *E. coli* and *Pasteurella* infections in turkeys, as a drug of last resort.

For these reasons the AAAP urges you to include a veterinarian on your review committee who has great depth of experience in the real world practice of poultry disease diagnosis and prevention and is well-grounded in the principles of Food Safety. Our organization believes that the important decision-making that lies before you will be well-served by such an appointment.

Respectfully submitted,



Charles L. Hofacre
Secretary-Treasurer, AAAP

CLH/sc

Cc:

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

AAAP Board of Directors



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 29, 2004

Charles L. Hofacre
Secretary-Treasurer
American Association of Avian Pathologists
953 College Station Road
Athens, Georgia 30602-5875

Dear Mr. Hofacre:

Thank you for your letter of September 2 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

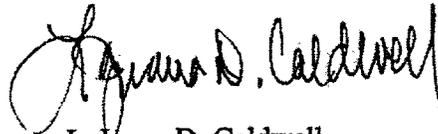
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administrative law judge issued an initial decision on March 16, 2004. The parties have filed exceptions to the initial decision.

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,

A handwritten signature in black ink, appearing to read "Lajuana D. Caldwell". The signature is fluid and cursive, with the first name being the most prominent.

Lajuana D. Caldwell
Director
Office of Executive Secretariat

cc: Dockets Management Branch (HFA-305)