

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

RE: Docket N^o 00N-1571, Enrofloxacin for Poultry

This submission is made on behalf of the more than 210 Diplomates of the American College of Poultry Veterinarians. This professional association, chartered in 1991 by the American Board of Veterinary Specialties, a constituent body of the American Veterinary Medical Association, promotes the health and productivity of commercial poultry and indirectly contributes to the well-being of US citizens by providing wholesome eggs, turkey and broiler meat with an aggregate value exceeding \$20 billion annually. Diplomates of the College are involved in a number of activities including disease prevention, production management, diagnostic services, technical support for biologics and pharmaceutical manufacturers, and primary breeders. Diplomates are also involved in regulatory activities at the Federal and State levels and are responsible for research and instruction of professional and post-graduate students.

The manufacturer and distributor of Baytril, the commercial formulation of enrofloxacin, responded to the Notice of Opportunity for Hearing on February 21, 2001, submitting facts, information and analyses. The manufacturer submitted a narrative statement pursuant to 21 CFR 12.85(a)(4) on April 22, 2002, further outlining the scientific evidence for retention of the drug approval, in accordance with NADA 140-828.

It is the contention of the College that the review of scientific literature and the facts as interpreted in the narrative statement of the Respondent do not justify withdrawal of Baytril if used in accordance with initial approval for use in poultry in 1996.

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The justification for this position is summarized:

- There are no specific epidemiologic data to associate the quantitative or temporal relationship of quinolone resistant *Campylobacter* spp. in humans with the administration of Baytril as a therapeutic compound in either turkeys or chickens.
- The initial risk analysis (Vose study) which formed the basis of the FDA initiative during 2000, incorporates incorrect assumptions. It is flawed in that it fails to follow the National Academy of Science model for risk assessments and specifically ignores pathogen load (dose response) as a critical factor in estimating the number of consumers potentially impacted. The study results were biased by incorrect assumptions based on selected data that are not representative of the US population. The study over-estimated the extent to which chicken is a vehicle of human *Campylobacter* infections and failed to consider that the prevalence of *Campylobacter* infections in the US is declining. The study has been widely criticized by experts in risk assessment and has not been validated.

Based on the absence of new scientific evidence to the effect that Baytril represents a potential human health hazard, it is earnestly requested that the approval of the drug be continued under the following conditions:

- Intensified and structured surveillance of patterns of drug resistance applying advanced molecular biological techniques.
- Completion of a valid scientific risk analysis incorporating accurate and relevant data.
- Intensification of Prudent Use Principles and Guidelines in poultry, which govern the prescription of the product.
- Investigation of other potential mitigation strategies to minimize the selection and dissemination of resistant pathogens such as:
 - Administration of Baytril on the basis of mg/kg of bodyweight in place of the current practice of volumetric dosing.
 - Scheduling treated flocks to be processed following untreated flocks at the processing plant.
 - Biosecurity measures to prevent possible lateral transmission of drug-resistant organisms from treated flocks to adjoining units.

The American College of Poultry Veterinarians is concerned that the FDA will withdraw approval for Baytril without considering and appraising in detail, all published scientific data, thereby depriving licensed veterinarians, many of whom are in addition, Board-certified as poultry health practitioners, of the right to exercise their professional judgment in prescribing this fluoroquinolone.

Thank you for your consideration of this matter:



Date: 9/3/02

Dennis P. Wages, DVM, Dipl. ACPV

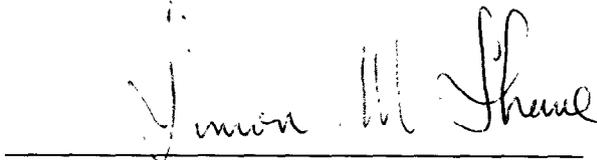
President, American College of Poultry Veterinarians



Date: 9/12/02

Fred J. Hoerr, DVM, PhD, Dipl. ACPV

President Elect, American College of Poultry Veterinarians



Date: 9/14/02

Simon M. Shane, FRCVS, BVSc, PhD

Dipl.ACPV Ad Hoc Committee



Date: 9-10-02

Greg J. Cutler, DVM, MPVM

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