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December 31, 2000

00N-1571 C18

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

Reference: Review of Docket No 00N-1571, Enrofloxacin for Poultry; Notice of Opportunity for Hearing

Dear Sir or Madam:

The members of the American Association of Bovine Practitioners are veterinarians with a commitment to providing healthful consumer products from cattle, maintaining and improving the health of cattle and assisting cattle owners achieve sustainable production from the natural resources they utilize. As the Chairman of the AABP Committee on Pharmaceutical and Biologic Issues at the time the notice for the opportunity for hearing was announced, I offer the following comments.

The preponderance of evidence does not support the action to withdraw poultry fluoroquinolone approvals. The current proportion of human cases of campylobacterial infection requiring antibiotic treatment and resistant to antibiotic treatment due to the use of enrofloxacin in poultry was not used in the risk assessment. The proportion of cases estimated in the risk assessment used information that was over a decade old and did not reflect current guidelines for use of antibiotics in either humans or animals. The risk assessment acknowledged there was a range of etiologic fractions associated with the risk factors for fluoroquinolone resistant campylobacterial infections and that the relationship between resistant campylobacterial infections in poultry and resistant infection in humans is uncertain.

Additionally, the proposed action and the earlier risk assessment do not address the probability of achieving the desired reduction in antibiotic resistant infections of human campylobacterial infections. While the immediately preceding paragraph questions the importance of the removal of enrofloxacin use in poultry, there is no evidence available that shows that the removal would result in significantly less antibiotic resistant campylobacterial infections in humans. From an uncertain association of resistant camplobacterial infections in poultry and humans, the conclusion is made that removal will result in less human resistant infections. Further, the cost in animal suffering and loss with the removal of enrofloxacin use in poultry is not estimated. How can the withdrawal be justified without an estimate of the proposed benefit or the resulting costs to poultry production?

The proposed action appears to be arbitrary and therefore would undermine the faith and support for actions based on evidence and complete and current assessments of risk.

Sincerely yours,

Lloyd L Knight, DVM

Lloyd L. Knight, D.V.M.

AMERICAN ASSOCIATION OF BOVINE PRACTITIONERS

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