

FINDING OF NO SIGNIFICANT IMPACT  
for

BAYTRIL® 3.23% Concentrate  
(Enrofloxacin 3.23% Water Additive Solution )  
for Poultry

NADA 140-828

Bayer Agricultural Division, Animal Health  
Shawnee Mission, KS

The Center for Veterinary Medicine (CVM) has considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement will not be required.

Bayer Agricultural Division, Animal Health has submitted a New Animal Drug Application (NADA) 140-828 for BAYTRIL® 3.23% (Enrofloxacin 3.23% Water Additive Solution) Concentrate for poultry (turkeys and chickens). Enrofloxacin is a fluoroquinolone antibiotic. The intended use of enrofloxacin 3.23% water additive solution is for the treatment of *Escherichia coli* infections in chickens and *E. coli* and *Pasteurella multocida* (fowl cholera) infections in turkeys. The label dose is 25 to 50 ppm in drinking water for 3 to 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Bayer has submitted a February 1996, environmental assessment (EA, copy attached) for the approval of this application. The EA includes information on the manufacture and use of enrofloxacin.

Bayer has submitted a data package to address the potential environmental effects from the use of enrofloxacin and its major metabolite, ciprofloxacin. The data package contains physical/chemical, and environmental fate and effects studies for enrofloxacin and ciprofloxacin. Enrofloxacin will be introduced into the environment through land application of poultry waste. Enrofloxacin residues are sorbed in poultry wastes and become tightly sorbed when wastes are incorporated into soils and expected to remain appreciably bound in soils. Information provided in the EA demonstrates that sorption dramatically reduces the toxicity and bioavailability of enrofloxacin residues to plants and microorganisms. Based on the exposure estimates and toxicity data, enrofloxacin and ciprofloxacin entering terrestrial or aquatic environments are not expected to have significant effects on terrestrial or aquatic organisms.

The possibility of enrofloxacin residues in environmental media to select for resistant microorganism was considered by CVM. Because enrofloxacin is tightly bound to soil

and sediment, and not anticipated to be bioavailable, selection pressure for resistance in environmental microorganisms is not likely to occur.

The submitted EA provides adequate information to determine that the manufacture and use of enrofloxacin in poultry would not be expected to cause a significant impact on the environment.

7-5-96

Date

R. C. Livingston

Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: Environmental Assessment dated February, 1996, and Attachments