FINDING OF NO SIGNIFICANT IMPACT
for

BAYTRIL®
(Enrofloxacin)
100 Injectable Solution
for Cattle

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 has submitted a New Animal Drug Application (NADA) for BAYTRIL®(enrofloxacin) 100 Injectable Solution for Cattle. Enrofloxacin is a fluoroquinolone antibiotic. The intended use of BAYTRIL® 100 is for the treatment of bovine respiratory disease (BRD). The product will be used in cattle on feedlots, cow-calf stocker operations, pastures, and farm feeders at a dose of 2.5 to 5.0 mg/kg body weight(b.w.) for 3 to 5 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 cattle manure. Enrofloxacin residues are sorbed and become tightly bound to soils and sediment. 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 microorganisms 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 BRD would not be expected to cause a significant impact on the environment.

1-17-97 — Date

R. C. Livingston — Director, Office of New Animal Drug Evaluation, HFV-100

Attachments: February, 1996 Environmental Assessment