

FINDING OF NO SIGNIFICANT IMPACT

for

**Colistimethate Sodium
for 1-3 Day Old Chickens**

**ALPHARMA Inc.
Fort Lee, NJ**

**FOR PUBLIC DISPLAY
(HFA-305)**

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

Alpharma Inc., has submitted a new animal drug application for colistimethate sodium (FIRST GUARD™) for the control of colibacillosis in 1-3 day old chickens. In support of the application, the drug sponsor has submitted an environmental assessment (EA, dated June 1996) under 21 CFR 25.31a(a).

The sponsor voluntarily submitted a full EA under 21 CFR 25.31a(a) that addresses the environmental impact of the manufacture and use of the product. This action could have been handled as an abbreviated EA under 21 CFR 25.31a(b)(4) for prescription products. The Center has determined that prescription drugs, because of their limited use, will generally require the preparation of an abbreviated environmental assessment (AEA) under 21 CFR 25.31a(b)(4) and not a full EA as described under 21 CFR 25.31a(a). Unless the Agency has information to demonstrate, or is made aware of information that demonstrates potential environmental effects due to toxicity of a prescription drug, the AEA format should be used.

The June 1996 EA provides information on manufacturing, emissions, control exercised on emitted substances, fate and effects of emitted substances, and the firm's compliance with applicable environmental and occupational requirements at the site of product manufacture. The firm has submitted to a data package to address the potential environmental effects from the use of colistimethate in the environment. The data package contains physical/chemical, and environmental fate and effects studies for colistimethate.

The EA and supporting information do not indicate that there are potential environmental effects expected to occur from the manufacture and use of colistimethate sodium.

1-29-97
Date

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

Attachments: June 1996, Environmental Assessment