

FINDING OF NO SIGNIFICANT IMPACT

for

NADA # 012-123

GALLIMYCIN (erythromycin injectable)
for Cattle

Sanofi Animal Health, Inc.
Overland Park, KS

The Center for Veterinary Medicine has carefully 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 and that an environmental impact statement therefore will not be prepared.

Sanofi is requesting the approval of a supplemental NADA to revise the labeling of GALLIMYCIN (erythromycin 200 mg/ml) Injectable to include only the National Academy of Science/National Research Council - Drug Efficacy Study Implementation (DESI) labeling. The DESI indication is for the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with specific microorganisms. The dosage will be increased from 2 mg/pound body weight to 4 mg/pound body weight, and the duration of treatment will be limited to no more than five days.

The amount of erythromycin introduced into the environment under the proposed label is expected to be less than that introduced from previous uses. This is because, 1) the proposed labeling reduces the number of claims and, 2) some of the previous indications required treatments of longer duration than would be permitted under the proposed labeling. Therefore, the primary environmental concern is to demonstrate that the manufacturing of the product is not expected to have a significant impact on the environment.

In support of the supplement, Sanofi has provided the attached environmental assessment (EA) that was signed on May 1, 1992. The EA includes an EA from the bulk manufacturer, Abbott Laboratories, and an EA from the finished manufacturer, Boehringer Ingelheim, Ltd. The Abbott and Boehringer EAs provide adequate information concerning the control of solid, liquid and gaseous waste and occupational exposures to determine that the manufacture of the bulk and finished drug product is not expected to have a significant impact on the environment. Additionally, the Sanofi EA provides an assessment of the fate and potential effects from the proposed use. The information provided in addition to the expected reduction in environmental introductions of erythromycin are sufficient to conclude that the proposed use of the product to treat bovine respiratory disease is not expected to have a significant impact on the environment.

8/12/92
Date

Robert A. Bloom for CEE III
Preparer and Chief,
Environmental Sciences Staff, HFV-152

6/12/92
Date

Termin W. Lister for Dean McKee
Primary Action Officer
Generic Animal Drug and Quality Control Staff, HFV-102

Attachment: Environmental Assessment, signed May 1, 1992