

FINDING OF NO SIGNIFICANT IMPACT**PAYLEAN® (ractopamine HCl) Type A Medicated Article****for****Swine Feed****Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN**

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, therefore, an environmental impact statement will not be prepared.

This finding of no significant impact provides for the approval of a new animal drug application (NADA) for PAYLEAN® (ractopamine HCl) Type A Medicated Article for use in swine feed. The product is to provide for improved feed efficiency and increase carcass leanness. The product will be used continuously between 4.5 and 18.2 grams per ton of feed.

In support of the approval of the NADA, Elanco Animal Health has submitted an environmental assessment (copy attached) dated November 1995.

Information on the potential environmental impacts of the manufacturing of the product has been provided in the EA. However, this information is no longer necessary for approval of the NADA. Therefore, the FONSI does not address potential impacts from the manufacturing of PAYLEAN® Premix. The Environmental Protection Agency permitting process will handle manufacturing effluent issues.

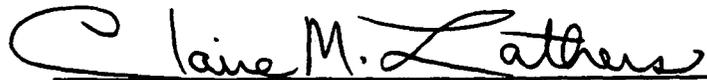
Information on the potential impact from the use and disposal of the product are also contained in the EA. The EA provides data to estimate the exposures and effects of ractopamine. In the EA, ractopamine exposures in soil are based upon a 10 ton per acre application rate of swine manure to agricultural soils. During the analysis of the data, CVM estimated an exposure based upon an application rate of 20 tons per acre. Twenty tons per acre is considered an appropriate application rate for swine manure (Livestock Waste Facilities Handbook, Second Edition, 1985, Midwest Plan Service Publication, MWPS-18). Based upon the information provided in the EA, and an exposure estimated from a 20 ton per acre application rate, ractopamine is not expected to be introduced into the environment at concentrations that are toxic to the indicator organisms for terrestrial and aquatic vertebrates, invertebrates, microbial organisms and plants. Although it is possible that organism exist that may be more sensitive to ractopamine than the indicator organisms, it is appropriate to determine, from the available data, that impacts on environmental organisms are not anticipated.

There is some indication that worms and possibly other invertebrates inhabiting manure could experience morbidity from exposure to ractopamine. Earthworms (*Lumbricus terrestris*) exhibited reduced growth rate when exposed to 30.9 ppm of soil incorporated ractopamine. The next lowest concentration tested, 8.11 ppm did not change weight gain. Since there is a potential for the concentration of ractopamine in manure to be as high as 11.9 ppm, there is some potential for effects to occur. The expected degradation of ractopamine reduces the potential for impacts, but vermiculturists should use precaution, such as dilution, if utilizing manure containing ractopamine.

Information in the EA also addresses potential occupational impacts at the site of mixing for the final feed containing PAYLEAN®. The information indicates that precautions are needed when handling PAYLEAN® and the labeling will contain information for the safe handling of the product. Occupational effects are further addressed in the FOI summary.

The EA is adequate to determine that the proposed approval of ractopamine in PAYLEAN® will not have a significant impact on the human environment.

7/8/99
Date


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

Attachments: November 1995 Environmental Assessment