

FINDING OF NO SIGNIFICANT IMPACT

for

OXYTET SOLUBLE (Oxytetracycline Hydrochloride Water Soluble Powder)
for Use in Swine

NADA 130-435 C027

I.D. Russell Co., Laboratories
Kansas City, MO 64141


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. Therefore, an environmental impact statement will not be required.

I.D. Russell Co. requested approval of a supplement to NADA 130-435 for the use of OXYTET SOLUBLE (oxytetracycline hydrochloride water soluble powder) in swine. The supplement provides that oxytetracycline would be administered in drinking water, as a drench or with an oral dose syringe to control and treat bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis, and bacterial pneumonia caused by Pasteurella multocida (for a treatment duration of up to 5 days. Another treatment (for a duration of 7 to 14 days) is indicated to reduce the incidence of abortions caused by Leptospira pomona in breeding swine. The drug is to be administered to swine in drinking water at a dose of 10 mg/lb body weight for each indication.


I.D. Russell Co. provided the attached environmental assessment (EA) dated January 9, 1989, in support of the approval of this supplement. The EA indicates that the product will be manufactured by I.D. Russell Co. in Kansas City, MO, and certifies that the manufacturing facility complies with all applicable local, State and Federal environmental (including occupational) requirements.

An EA addressing the potential environmental impacts resulting from the uses of oxytetracycline proposed in this supplement, in addition to other uses approved by the National Academy of Sciences/National Research Council, was prepared by the Center for Veterinary Medicine in October of 1983 (also attached). The Center's EA contains information which documents that excreted oxytetracycline degrades rapidly in the environment, has a very low potential to bioaccumulate, and has a low potential to be toxic to organisms present in the environment, at the concentrations expected to occur.

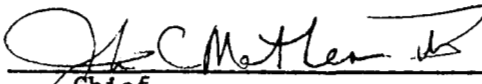
2/28/89
Date


Preparer,
Environmental Sciences Staff, HFV-162

2-28-89
Date


Primary Action Officer, HFV-133

2/28/89
Date


Chief,
Environmental Sciences Staff, HFV-162

Attachments (2)