Date June 26, 1979

ENVIRONMENTAL ASSESSMENT REPORT OF NOVOBIOCIN IN DUCKS

The environmental assessment of this action has been accomplished on the basis of a complete environmental impact analysis report. It is concluded that the proposed action will not have a significant impact on the quality of the human environment and that an environmental impact statement is not needed.

Thomas V. Raines

Thomas V. Raines, D.V.M.
Primary Action Officer

Donald A. Gable 6-27-79

Donald A. Gable, D.V.M.
Environmental Impact Coordinator
for Preclearance

Kenneth E. Taylor 8/31/79

Kenneth E. Taylor, D.V.M.
Director, Environmental
Impact Staff

Enclosures:

Environmental Impact Analysis Report
Environmental Assessment Report

ENVIRONMENTAL ASSESSMENT REPORT OF NOVOBIOCIN IN DUCKS

A. Summary of Action

The Upjohn Company is requesting approval of the use of Novobiocin in duck feed for the control of infections serositis and fowl cholera in ducks caused by strains of Pasteurella anatipestifer and P. multocida respectively, susceptible to Novobiocin. It will be administered in the feed at the rate of 350 grams Novobiocin per ton as the sole ration from 5 to 7 days. Medication may be continued for 14 days if necessary or repeated if the infection recurs. There is a 3 day drug withdrawal period required before slaughter.

B. EVALUATION

There are two methods of husbandry utilized in duck growing, i.e.; the "wet lot" system provides ponds for the birds for drinking and swimming and the "dry lot" system where the duck droppings or solid wastes are spread on farm or nursery lands.

I. Regarding the wet lot method, a study was conducted by the Cornell University Duck Research Laboratory in Eastport, New York. A commercial flock of ducks with access to a pond for swimming was fed Novobiocin at a dosage of 350 grams/ton of feed for 7 days. On the last day of medication, daily collection of pond waste samples were taken and continued for 7 days. Each sample was taken in a location in the pond which was accessable to and frequented by the ducks. At the same time, water samples were taken from the effluent of the water treatment facility which handled the water from the treated duck pen. This was done to determine the persistence of Novobiocin in the environment.

The excretion of Novobiocin was also determined utilizing ducks treated with Novobiocin at the calculated recommended level administered by gavage and comparing them with non-medicated ducks.

A microbiological assay was used. The assay organism was Staphylococcus epidermidis. The sensitivity of the assay method was 0.02 mcg/ml. Novobiocin was detected from the pond for four days following the end of treatment at only very low levels, i.e., 0.02 - 0.07 mcg/ml. After 4 days they were below the detection of 0.02 mcg/ml. All samples from the effluent of the water treatment which handled the water failed to give a detectable level of Novobiocin.

From duck excreta and cage washings from the treated ducks the estimated recovery of Novobiocin was 33.1% with 97.3% found during the first 24 hours and over 99% in the first 48 hours.

The stability of Novobiocin in duck feces is unknown, but the characteristics of the compound indicate that the temperature and moisture in this medium would expedite its complete degradation in a relative short time. Novobiocin is also sensitive to light.

II. Duck droppings are spread on farm land. The high nitrogen content limits application to one or two tons per acre, not to exceed three tons. This would be blended into the top 8 inches of soil. This mixture would result in a maximum Novobiocin concentration of 600 mcg/kg (ppb). The maximum potential concentration of Novobiocin in the soil from spreading 3 tons of duck manure to the acre (worst possible situation) is very much lower than the 20 and 40 parts per million found to have no adverse effect on soil and water organisms.

Upon equilibration in an oil/water system , 100% distribution of Novobiocin into the organic oil phase occurs. We have considered this but have concluded that the short term use of Novobiocin in duck feed would not be of biological significance to the ecosystem.

Up to 40 parts per million Novobiocin had no effect on the following soil organisma: Psuedomonas fluorescens, Aspergillus niger and Chlorella pyrenoidosa. We have carefully considered the fact that no soil leaching studies or phytotoxicity studies were done with Novobiocin.

The drug has a wide margin of safety in fish. The 96-hour LC 50 in bluegills was in excess of 1,000 parts per million.

The results of the extensive laboratory studies, i.e., acute, subacute, and chronic as well as teratology studies reported in the appendices and the EIAR indicate that there should be no danger to wild life . These data have been reviewed and found to be satisfactory.

C. Conclusions

The proposed use of Novobiocin in ducks constitutes the minor use of a drug. The introduction of Novobiocin into the environment by raising ducks under the wet lot method and the dry lot method has been carefully considered. There is presently no approved drug for use against infectious serositis of ducks. We do not agree with statements made in the firm's EIAR that there are no drugs approved for use against fowl cholera in ducks. Chlortetracycline is approved for use against fowl cholera in ducks. However, the fact remains that there is presently no approved drug for use against infectious serositis of ducks. This is a serious epornitic of ducks which causes high mortality and morbidity. It is estimated that the incidence of infectious serositis is 50% of the growing ducks in Long Island and 33% of the growing ducks in other production areas of the United States. We have considered that the swimming pond water of the duck ponds in Long Island (the major duck producing area in the East) goes into settling tanks to remove solids; in the settling tanks also the water is aerated and chlorinated. Further consideration has been given to the fact that the effluent water meets the New York State and Federal requirements for entry of the effluent into the fresh water streams.

In Virginia and Wisconsin, waste water from duck growing operations is subjected to secondary treatment for retention in lagoons for aerobic microbiologic degradation.

We have further considered the use of duck droppings which because of their high protein content are limited to a maximum of 3 tons per acre

The lack of toxicity of the drug against soil microorganisms and its wide margin of safety to fish were also considered in concluding the lack of environmental effect.

There are no known public objections to the use of Novobiocin in duck feeds.

cc:
NADA, Orig. Dup HFV-16
Branch File HFV-149
Dr. Gable, HFV-=101
Hearing Clerk
TVRaines, HFV-149/dhb/6-13-79