FINDING OF NO SIGNIFICANT IMPACT

for

Rofenaid^{R} - 40 Premix for Ducks

NADA 40-209
Hoffman-LaRoche Inc.

The Bureau of 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.

Hoffman-LaRoche Inc. of Nutley, N.J. has filed a supplement to their new animal drug application (NADA 40-209) providing for the use of Rofenaid-40 medicated premix at a concentration of either 0.04% or 0.08% in feed for the prevention and treatment of several infectious diseases of ducks. Rofenaid-40 premix is presently approved at a concentration of 0.02% in feed as an aid in the prevention of several infectious diseases in broiler and replacement chickens, and at a concentration of 0.01% in feed as an aid in the prevention of coccidosis and fowl cholera in turkeys.

Rofenaid-40 is a feed premix which has a broad spectrum antibacterial and anticoccidial activity. This activity is due to the two active ingredients, sulfadimethoxine and ormetoprim, present as 25% and 15%, respectively, of the Rofenaid-40 premix. Sulfadimethoxine is a sulfonamide antibiotic which has been widely used in the treatment of a variety of infectious diseases in humans and in domestic animals. Ormetoprim is a pyrimidine which is used primarily to potentiate the antibacterial and anticoccidial activity of sulfadimethoxine.

Hoffman-LaRoche has filed the attached environmental impact analysis report (EIAR) in support of the proposed uses of Rofenaid-40 in ducks. The EIAR (attached) indicates that the proposed uses in ducks should result in relatively minor increases in the introductions of sulfadimethoxine and ormetoprim into the environment. In addition, this EIAR is adequate to conclude that these two drugs will occur at low concentrations in the aquatic and terrestrial environments, and at these concentrations are unlikely to result in significant environmental effects.

3-24-83
Date

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3/26/83
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cc: Orig. & Dup., NADA 40-209
File & Reading Board

MGZeeman/cbm/3/23/83