FINDING OF NO SIGNIFICANT IMPACT

for

Monteban® (Narasin) Premix for Broiler Chickens

NADA 118-980

Elanco Products Company
Indianapolis, IN

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.

Elanco Products Company, a division of Eli Lilly and Company, has filed the attached Environmental Assessment (EA), dated January 1986, in support of the proposed use of Monteban® (narasin) in broiler chickens. The EA asserts that the proposed use of Monteban® (narasin) as a coccidiostat in broiler chickens should result in levels of introductions of narasin into the environment that are not expected to result in effects upon organisms living in the environment. These assertions are based upon the firm's data and calculations in the EA.

This Finding of No Significant Impact (FONSI) provides additional interpretation of the environmental information submitted by Elanco and is also intended to augment the EA submitted by this firm by the inclusion of information not submitted as part of this EA.

Elanco Products Company has requested an approval of a new animal drug application (NADA 118-980) for the use of Monteban® premix in the feed of broiler chickens for the prevention of coccidiosis. Narasin is the active drug ingredient in Monteban® premix. Chemically, the drug narasin is a monocarboxylic polyether ionophore with a structure that is very similar to that of salinomycin, another ionophore which has been previously approved for use in broilers as a coccidiostat. Narasin is produced in a dried mycelial biomass form by a fermentation process. Monteban® contains enough dried fermentation product to result in narasin concentrations of 80, 100, 120, 160, or 200 grams (g) of activity per kilogram (kg) of premix. Between 60 and 80 parts per million (ppm) of narasin (from 54.5 to 72.6 g per ton of feed) would be used continuously in the feed of broiler chickens. Broilers must be taken off feed medicated with narasin three days before they are slaughtered.

The most important environmental information included in the attached EA indicates that: 1) narasin is rapidly metabolized by chickens and only 5% of the narasin is excreted by chickens given this drug, 2) there are at least 20 narasin metabolites in chicken excreta, with none being very predominant, 3) the metabolites in highest concentrations in the excreta have been determined to be of considerably less biological activity than the parent drug, 4) the narasin activity in soils incorporated with chicken excreta has been shown to decrease rather rapidly, and 5) narasin concentrations in water also appear to decline rather rapidly, due to decreased narasin activity via the the probable degradation of this chemical in water by sunlight and chemical processes.

The quantities of Monteban® (narasin) that could be sold for this proposed use in broilers will ultimately determine how much of this drug could potentially enter the environment. The market for this specific drug use in broilers would already appear to be somewhat saturated, as there are several other drug products already approved for this use in broilers. The products already approved are Biocox® (salinomycin), Coban® (monensin), Avatec® (lasalocid), and Stenoral® (halofuginone). Most of these compounds are also ionophoric chemicals with chemical structures and activities that are also similar to that of Monteban® (narasin). Therefore, it is reasonable to assume that the approval of this product should not result in any significant change in 1) the overall use of coccidiostats in broilers, and 2) the overall chemical introductions of such ionophoric compounds already entering the environment.

2-5-86
Date

M. Zeeman
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Date

Thomas F. Rainer
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2-6-86
Date

Chief, Environmental Staff, HFV-152

Attachment

cc: Orig. & Dup., (NADA 118-980)
Office File, HFV-152
Reading Board, HFV-152

MZeeman:cbm:2/5/86(#1.21)