

FINDING OF NO SIGNIFICANT IMPACT

Lasalocid (Avatec) for Use in Turkeys

NADA 96-298

Hoffmann-La Roche
Nutley, NJ 07110

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.

Hoffmann-La-Roche requested approval of a supplement to NADA 96-298 for the use of Avatec (lasalocid) in turkeys to prevent coccidiosis caused by three species of *Eimeria*. The product will be mixed into feed at a rate of from 68 to 113 g/ton (75 to 125 ppm) and be fed continuously to turkeys susceptible to coccidiosis. The rate of administration is the same as that approved for broilers under 21 CFR 558.311.

In support of the approval of this supplement, Hoffmann-La Roche provided the attached environmental assessment (EA) dated June 1989. The EA was subsequently updated on November 23, 1994, with the recent turkey production figures, updated manufacturing environmental permits and new certifying signatures. The EA provides environmental information concerning the manufacture and use of lasalocid for the prevention of coccidiosis in turkeys.

Some labeling mitigation for occupational exposures was necessary. The product labeling provides a warning to avoid contact with eyes, to use protective clothing, impervious gloves and a dust mask when mixing and handling lasalocid premix. Operators should wash thoroughly with soap and water after handling.

Hoffmann-La Roche certifies that the manufacturing facility complies with all applicable local, State and Federal environmental requirements.

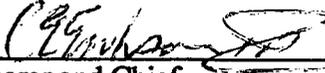
At present, 50% of the coccidiostats used in turkeys are ionophores with the other 50% using other coccidiostats. An optimistic projection is that lasalocid could be used for 50% of the ionophore applications or 25% of the total coccidiostat usage in turkeys. Therefore, the projected use of lasalocid for turkeys is estimated to be 2.6×10^6 tons.

This increase in usage for turkeys is not expected to affect the amount of lasalocid bulk substance produced at the facility in Belvidere, NJ, because the plant is reported to be at full production capacity. The net effect will be the reduction of export shipment volume as the use in turkeys increases in the USA. No adverse environmental impacts are expected from the additional manufacture of this product.

The metabolism of lasalocid in turkeys is reported to be similar to that in chickens. The lasalocid in moist turkey litter (in which lasalocid is the major single component) is reported to be approximately 10% of the total drug residue. Under aerobic conditions, lasalocid was reported to rapidly disappear. This is similar to the environmental analysis for broiler chickens.

Therefore, the available information indicates that the manufacture and use of lasalocid for the prevention of coccidiosis in turkeys is not expected to have significant effects on the quality of the human environment.

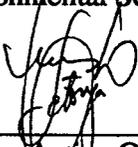
3/14/95
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Attachment: EA