FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION **NADA 96-298**

NADA SPONSOR:

Hoffmann-La Roche, Inc.
340 Kingsland Road
Nutley, New Jersey 07110-1199

a. Established Name:	lasalocid sodium
b. Trade/Proprietary Name:	Avatec®
c. Dosage Form:	Type A medicated article to be mixed with feed to produce a Type C medicated feed.
d. How Supplied:	50 lb (22.68 kg) bags
e. How Dispensed:	OTC
f. Amount of Active Ingredient:	Type A: 90.7 g/lb Type C: 68-113 g/ton (Broiler & Fryer Chickens) Type C: 113 g/ton (Chukar Partridges)
g. Route of Administration:	This drug is administered orally by adding the Type A medicated article to feed to make a complete feed (Type C medicated feed).
h. Species:	Broiler and Fryer Chickens and Chukar Partridges
i. Labeled Dosage:	Broiler and fryer chickens: 68-113 g/ton of Type C medicated feed to be fed as the sole ration continuously Chukar Partridges: 113 g/ton of Type C medicated feed to be fed as the sole ration continuously up to 8 weeks of age
j. Indications for Use:	Broiler and fryer chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E acervulina, E. maxima, E. brunetti,* and *E. mivati.* Chukar Partridges: For the prevention of coccidiosis caused by *Eimeria legionensis.*

This FREEDOM OF INFORMATION SUMMARY references data in Public Master File (PMF) 5429, 58 FR 39031, July 21, 1993, in support of the supplemental new animal drug application for chukar partridge. The data were generated by:

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2. TARGET ANIMAL SAFETY

Target animal safety data from the FOI summary for PMF 5429, 58 FR 39031, July 21, 1993, demonstrated that there was no drug-induced mortality or abnormality reported at any level tested. Lasalocid is safe for chukar partridges at the proposed level of 0.0125%.

3. DRUG EFFECTIVENESS:

Efficacy data from the FOI summary for PMF 5429, 58 FR 39031, July 21, 1993, demonstrated that a level of 0.0125% lasalocid in complete feed was effective in preventing coccidiosis in chukar partridges caused by *Eimeria legionensis,* based on reduction in mortality, reduction of parasite numbers in the jejunum and ileum, reduction of cecal core scores, and improved weight gains.

4. HUMAN FOOD SAFETY:

Toxicity Tests: Data regarding toxicity testing are contained in the approved NADA.

5. AGENCY CONCLUSIONS:

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that lasalocid sodium, when used under the proposed conditions of use, is safe and effective for the prevention of coccidiosis caused by *Eimeria legionensis* in chukar partridges.

Human food safety data which have been submitted under PMF 5429, 58 FR 39031, July 21, 1993, indicate that lasalocid will be used to treat coccidiosis which is a disease of young chukar partridges up to the age of 8 weeks. As the birds are not released or marketed until the age of 18 to 20 weeks, these conditions result in an inherent withdrawal time of at least 10 weeks after administration. Based on this and the characteristics of lasalocid sodium drug metabolism, the Agency has concluded that tissue residue deletion data was not necessary for satisfying human food safety concerns.

The original approval of lasalocid sodium was as an over-the-counter drug. Accurate diagnosis of coccidiosis in chukar partridges, which is the new species to be added to the label, can be made with reasonable degree of certainty by the layman. Adequate directions for use have been written for the layman, and the conditions for use prescribed

on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall have over-the-counter marketing status.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change. The approval of this change did not require a reevaluation of the safety or effectiveness data in the parent application.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

Attachments:

The following labeling is attached.

Facsimile Type A medicated article labeling

Facsimile bluebird labeling for Type C medicated feed

Currently approved product labeling for Type A medicated article