I. GENERAL INFORMATION

NADA Number: 096-298

NADA SPONSOR: Roche Vitamins, Inc.
45 Waterview Boulevard
Parsippany, New Jersey 07054-1298

Established Name: lasalocid sodium

Trade Name: BOVATEC® Type A Medicated Article

Marketing Status: over-the-counter

Effect of Supplement: A new species and class (young rabbits) approved under the NADA for AVATEC© is added to the BOVATEC© Type A medicated article label

II. INDICATIONS FOR USE

For the prevention of coccidiosis in young rabbits caused by *Eimeria stiedae*.

III. DOSAGE FORM

The Type A medicated article is to be mixed with feed to produce a Type C medicated feed formulated to provide 113 g lasalocid/ton. The Type C medicated feed should to be fed as the sole ration for young rabbits up to $6^1/_2$ weeks of age.

IV. EFFECTIVENESS

Effectiveness data from the FOI summary for PMF 5042 (55 FR 9771; March 15, 1990) demonstrated that lasalocid sodium, at a level of 113 g per ton of feed (125 ppm), was effective for the prevention of coccidiosis caused by *Eimeria stiedae* in young rabbits.

V. TARGET ANIMAL SAFETY

Target animal safety data from the FOI summary for PMF 5042 (55 FR 9771; March 15, 1990), demonstrated that administration of lasalocid sodium in feed has a reasonable margin of safety in rabbits. Lasalocid is safe to rabbits when used at the dosage level of 125 ppm (1x) in feed for a period of up to of six weeks.

VI. HUMAN FOOD SAFETY

A. Toxicity Tests:

Data regarding toxicity testing for lasalocid are contained in the original NADA and Freedom of Information (FOI) Summary for AVATEC® under NADA 096-298 (41 FR 44381; Oct. 8, 1976).

B. Withdrawal period:

This submission provided CVM with the opportunity to codify a tolerance for lasalocid in rabbits. Accordingly, the Agency is assigning the cattle liver tolerance of 0.7 ppm parent lasalocid (the marker residue) to rabbit liver (the target tissue).

Data regarding residue depletion for lasalocid are contained in the Public Master File (PMF 5042) and Freedom of Information (FOI) Summary for the use of lasalocid as a coccidiostat in rabbits (55 FR 9771; March 15, 1990).

According to CVM's withdrawal time statistical program, lasalocid residues in rabbit liver deplete to less than 0.7 ppm at 5 days after the last treatment. The 5 days necessary for depletion is accommodated by the 10 days inherent withdrawal time between last treatment and possible slaughter. The inherent withdrawal time is discussed in the FOI for the original approval for lasalocid in rabbits under this NADA.

C. Regulatory Method:

The validated analytical method is discussed in the original NADA and Freedom of Information (FOI) Summary for AVATEC® under NADA 096-298.

VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at part 514 of Title 21 of the Code of Federal Regulations (21 CFR 514). The data demonstrate that BOVATEC® Type A medicated article, when added into feed at a rate of 113 g lasalocid/ton to make a Type C medicated feed (fed as the sole ration for a period of no longer than 6 weeks), is safe and effective for the prevention of coccidiosis due to *Eimeria stiedae* in young rabbits up to $6^1/_2$ weeks of age.

In accordance with 21 CFR 514.106(b)(2), this is a category II change. While not required for the approval of this supplemental application, the Center has taken the opportunity to codify a tolerance of 0.7 ppm parent lasalocid in rabbit liver.

The original approval of lasalocid sodium was as an over-the-counter drug. Accurate diagnosis of coccidiosis in rabbits, 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.

The agency has determined under 21 CFR 25.33(a) that these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. APPROVED LABELING (attached)

Facsimile bag label - BOVATEC® Type A medicated article

Specimen (Blue Bird) label - Type C medicated feed