I. GENERAL INFORMATION

A. File Number

NADA 096-298

B. Sponsor

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110

C. Trade Name

AVATEC

D. Generic Name

lasalocid sodium

E. Marketing Status

Over the Counter (OTC)

F. Effect of Supplement

Adds an additional claim for the prevention of coccidiosis in growing turkeys with a zero (0) day withdrawal time. The use level in feeds approved for broiler chickens at 68 to 113 grams per ton of feed (75-125 ppm) remains the same

II. INDICATIONS FOR USE

For the prevention of coccidiosis in growing turkeys caused by Eimeria meleagrimitis , E. gallopavonis and E. adenoeides .

III. DOSAGE

A. DOSAGE FORM: As complete turkey feeds manufactured from Avatec Type A medicated article (21 CFR § 558.311). For oral use via medicated feed providing lasalocid in the range of 68 to 113 grams per ton (75-125 ppm) of feed.
B. ROUTE OF ADMINISTRATION: See above
C. RECOMMENDED DOSAGES: See above

IV. EFFECTIVENESS

A. Pivotal Battery Study

Dr. Larry McDougald, Athens, Georgia, conducted a coccidial challenge dose titration study as follows. Lasalocid was titrated in two-week old turkeys challenged with single or mixed species of coccidia in a well-controlled battery study. Lasalocid was added to the ration for eight days, beginning two days before inoculation, at 0, 75, 125 and 175 ppm; an uninfected unmedicated group (UUC) was included. Each infected treatment group and the UUC group were assigned to four pens (two males, two females) of 10 turkeys each.

The results were as follows:
Infected

	UUC*	Lasalocid ppm			
		0 (IUC)	**75**	**125**	**175**
Weight Gain	222				
E. adenoeides		124	211	218	217
E. gallopavonis		106	201	216	220
E. meleagrimitis		105	205	217	211
Mixed Infections		61	207	217	212
Feed Conversion	139				
E. adenoeides		2.09	1.46	1.41	1.39
E. gallopavonis		2.35	1.53	1.46	1.37
E. meleagrimitis		2.33	1.48	1.43	1.43
Mixed Infections		5.03	1.49	1.41	1.42
Lesion Scores	0				
E. adenoeides		3.19	1.13	.69	.75
E. gallopavonis		3.44	1.44	1.25	1.06
E. meleagrimitis		3.75	1.81	1.38	1.25
Mixed Infections		9.75	5.50	3.63	2.94

*common control

Lasalocid at all levels was effective in controlling the infections of single or mixed species of coccidia as measured by weight gain, feed conversion and lesion scores when compared to infected, unmedicated controls (IUC). Lesion scores were determined by direct examination of the intestines and were rated from 0 (normal) to 4 (life threatening). In the group that received mixed infections, the lesion scores are higher than 4 because the scores of each affected portion of the intestine are added.

No coccidiosis mortality occurred in lasalocid-medicated groups while coccidiosis mortality of 2.5% (***E. adenoeides***), 7.5% (***E. gallopavonis***) and 7.5% (mixed) occurred in the IUC groups. No adverse drug effects were observed. These data confirm that the effective lasalocid dosage range is 75-125 ppm (68-113 g/ton) in the diet.

B. Pivotal Floor-Pen Studies

Dr. Larry McDougald, Athens, Georgia, conducted a well-controlled floor-pen study using 40, day-old male turkey poults started in each of 18 pens for 10 weeks. There were three lasalocid treatments (0, 75, and 125 ppm) with 6 floor pens randomly allocated to each treatment.

At 14 days of age poults were infected with recent mixed field isolates of ***E. adenoeides, E. gallopavonis*** and ***E. meleagrimitis*** by direct exposure in the feed. Five poults of each pen were sacrificed and lesion scores determined on days 21 and 28 of the study. The following results were obtained:

Lasalocid ppm	Body Weight (Kg)		Feed Conversion		Coccidiosis Mortality	Lesion Scores*	
	4 Wk	10 Wk	4 Wk	10 Wk		Day 21	Day 28
0	0.675	3.871	2.037	2.627	58/240	9.433	4.667
75	0.949	4.500	1.557	1.999	1/240	0.967	0.433
125	1.009	4.590	1.410	1.887	0/240	0.300	0.200

* Single Infection: 0 = normal, 4 = life threatening Mixed Infection: The lesion scores are higher than 4 because the scores of each affected portion of the intestine are added.

Lasalocid at all levels was highly effective in preventing coccidiosis as measured by weight gain, feed conversion, lesion score, and mortality when compared to infected unmedicated controls. One bird died with coccidiosis when medicated with lasalocid at 75 ppm and none died with coccidiosis when medicated at 125 ppm. Infected, unmedicated birds experienced a 24.17% mortality (58/240).

It was concluded that lasalocid at 75 and 125 ppm in the diet was effective in reducing lesion scores and mortality in young male turkeys when challenged with mixed infections of ***E. meleagrimitis, E. gallopavonis*** and ***E. adenoeides*** . Dr. Paul Waibel, St. Paul, Minnesota, conducted a controlled floor-pen challenge study using mixed field isolates of ***E. meleagrimitis, E. gallopavonis*** and ***E. adenoeides***. The efficacy of lasalocid anticoccidial activity was evaluated in 540 Large White Nicholas strain female turkey poults in floor-pens under simulated commercial conditions. The turkey hens were divided into three groups of six replicate pens each and received either a nonmedicated diet or 75 ppm or 125 ppm lasalocid continuously from day zero to 10 weeks of age. The turkeys were challenged with the field isolates of coccidial oocysts mixed in the feed at 14 days of age and scored for coccidial lesions seven days later.

The experimental design and overall responses were:

Lasalocid ppm	Replicates	Body Weight Kg	Feed Conversion	Coccidiosis	
				Percent Mortality*	Lesion Scores**
0	6	3.61	2.07	13.3	2.85
75	6	4.06	1.97	0	1.27
125	6	4.15	1.94	0	1.19

* 10 weeks
** 21 days, 1 = normal, 4 = life threatening.

Female turkeys medicated with 75 ppm or 125 ppm dietary lasalocid and challenged with mixed coccidial oocysts at 14 days of age had heavier body weights, better feed conversion and lower mortality at 10 weeks of age when compared to infected, nonmedicated female turkeys. Also, both groups of lasalocid-medicated turkeys had lower coccidial lesion scores seven days post-coccidial exposure than the infected, nonmedicated group. These results support the claim that lasalocid is an excellent anticoccidial compound in female turkeys when added to diets over a range of 75 ppm to 125 ppm. No adverse drug

reactions were observed. No adverse or unusual litter conditions were noted. Leg and feather conditions were within normal limits.

C. Corroborative Studies, Commercial Production

Dr. Larry McDougald, Athens, Georgia, conducted a controlled, unchallenged study in turkeys. Two hundred sixty-four female and 204 male turkey poults (Nicholas commercial type broad-breasted white turkey breed) were fed in a floor-pen study from hatch to market age (15 weeks for female and 20 weeks for male birds). Male and female birds were housed in separate pens with 17 males and 22 females per pen. Three pens of males and three pens of females were assigned to each of four treatments, 1) unmedicated feed; 2) lasalocid 75 ppm; 3) lasalocid 125 ppm; and 4) monensin 100 ppm. Brooding heat was provided as needed by electric heat bulbs and gas heaters. The building was of conventional construction with side curtain allowing natural ventilation. Lighting was provided by evenly spaced 40 watt bulbs mounted on the ceiling. Turkeys were randomly assigned to pens and pens were randomly assigned to treatment. The following was observed:

	Final Body Weight (Kg)		**Feed Conversion**	
Treatments	**Females 15 Weeks**	**Males 20 Weeks**	**Females 15 Weeks**	**Males 20 Weeks**
Unmedicated	7.145	11.628	2.816	2.726
Lasalocid 75 ppm	7.559	12.594	2.532	2.621
Lasalocid 125 ppm	7.220	11.786	2.554	2.863
Monensin 100 ppm	6.931	12.196	2.629	2.796

Dr. Jeffrey Davidson, Tulare, California, evaluated the utility and safety of continuous lasalocid medication in turkeys using commercial facilities and rations in 3,000 Nicholas Broad Breasted White, newly hatched female turkey poults. During the brooding period, 1 sq. ft/poult was provided, and after six weeks of age to market weight 2.25 sq. ft/poult was provided. The turkey hens were medicated with 113 g lasalocid/ton of feed, continuously from day one through 15 weeks of age, and nonmedicated withdrawal rations were fed to 17 weeks of age.

The results were as follows:

Average Bird Weights	16.96 lbs
Total Feed Intake/Total Slaughter Weight	2.52
Percent Mortality	1.20
Percent Culls	0.87

No adverse drug reactions, abnormal feathering, leg problems or abnormal litter conditions were observed.

The results of this study demonstrate the safety and utility of continuous lasalocid medication under commercial conditions in female turkeys.

Dr. Paul Waibel, St. Paul, Minnesota, conducted a commercial study with male turkeys using lasalocid. Ten thousand four hundred (10,400) Nicholas male turkeys were fed 113 g lasalocid/ton medicated feed from day one to 14 days prior to market at 17 weeks and 5 days. A control flock of the same number of birds was fed chlortetracycline for the first week and 50 g/ton zinc bacitracin to

market. The lasalocid treated birds were heavier, average 25.44 vs 25.27 pounds, had a slightly higher percent condemnation, 1.84 vs 1.03 and a slightly higher feed conversion, 3.002 vs 2.954.

The lower percent of grade A birds (64.8% lasalocid, 70.5% controls), as well as the higher percent of condemnation in the lasalocid group were attributed to poor weather conditions (blizzard) and a longer transport time to the processing plant. Treated turkeys and controls were not shipped to slaughter on the same date. It was concluded that lasalocid has commercial utility in current production methods.

Dr. James Sandstrom, Willmar, Minnesota conducted the following study. Lasalocid was provided in feed at 113 g/ton (125 ppm) at eight days of age to 10,000 male Nicholas turkeys and was withdrawn from feed three weeks prior to market at 17 weeks 5 days. Average weight gain was 25 pounds per bird and average feed conversion was 2.92. Total mortality of 5.28% was reported as lower than average for that location. There were no undesirable effects due to lasalocid. Litter condition, droppings, feathering and leg quality were equal to or better than expected industry results. Flock health indicated that coccidiosis was controlled. Dr. Dennis Rahn, Rice Lake, Wisconsin, conducted a commercial feeding trial with lasalocid in 23,046 Nicholas hens. Turkeys were started on lasalocid at 113 g/ton at day one and fed for 84 consecutive days. The average weight at 96 days was 13.6 pounds, feed conversion was 2.47, livability was 94.2%, Grade A's 89.7% and plant condemnation was 0.30%.

The conclusions were that the performance of turkey hens fed lasalocid was very good, feathering was excellent. No signs of toxicity due to lasalocid were noted. Feed conversion and percent Grade A were average for the location.

Mr. Roger James, Marshville, North Carolina, evaluated lasalocid under commercial conditions in 8,796 Nicholas Large White male turkeys fed continuously from day one at 113 g/ton until withdrawal 14 days prior to slaughter at 22 weeks of age. The livability was 85.66%, average weight was 35.36 pounds and feed conversion was 3.19 at 22 weeks of age. No clinical coccidiosis was evident. Early mortality was due to aspergillosis. No adverse drug effects were noted.

Dr. Jeffrey Davidson, Tulare, California, evaluated lasalocid at 113 g/ton under commercial conditions in 2,850 male and 4,500 female Nicholas Broad Breasted White turkeys from days one to 91 in females and days one to 108 in males. Medicated feed was withdrawn 15 days prior to slaughter at 106 days from the hens and 19 days prior to slaughter at 127 days from the males. The males had 93.9% livability, average live weight of 30.14 pounds and a feed conversion of 2.57; females 95.9% livability, average live weight of 18.1 pounds and a feed conversion of 2.35. No coccidiosis was observed, feathering and litter conditions were normal. No adverse reactions were noted.

Drs. L. Volker and O. Hurstel, Hoffmann-La Roche & Co. Ltd., Basle, Switzerland, and Neuilly S/Seine, France conducted a commercial feeding study of lasalocid at 90 ppm and 125 ppm in the feed involving a total of 40,480 young turkeys at five locations in western France (Brittany). Females were slaughtered at twelve weeks, males at 14-16 weeks. No problems were reported.

The investigators concluded that lasalocid at 90 ppm and 125 ppm provided prevention of coccidiosis under intensive large scale conditions practiced in western France.

A tabulation of performance data is below.

PERFORMANCE PARAMETERS OF BROILER TURKEYS RECEIVING 90 PPM OR 125 PPM LASALOCID IN THE FEED

Farm No	**1**		**2**		**3**		**4**		**5**	
Lasalocid ppm	90		125		90		125		90	
Sex	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
No. Birds	3600	3600	4720	4520	3760	3360	5720	5000	6200	
No. Days	97	80	101.5	84	110	91	108.5	84	105	91
Live Body Wgt. Slaughter (kg)	7.734	4.874	7.880	5.330	8.338	5.310	8.510	5.122	9.155	5.839
Avg. Body Wgt Slaughter (kg)	6.236		6.565		6.852		6.896		7.507	
Feed Conversion (g feed/g wgt gain)	1.044		2.220		2.346		2.505		2.268	
Percent Mortality	4.10		4.74		6.02		6.04		8.23	

V. TARGET ANIMAL SAFETY

A. Pivotal Studies

Target Animal Safety
A target animal safety study was conducted by Huntingdon Research Center, Huntingdon, England using lasalocid drug levels of 0, 125, 187.5, 250 and 375 ppm in feed. Male and female turkeys were fed from one day of age through 16 weeks.

The study was designed as shown in the following table.

	Treatment Lasalocid	**No. Replicates (Pens)**		**No. Birds per Replicate**	
Groups	**ppm**	**Males**	**Females**	**Weeks 1 & 2**	**From Weeks 3**
A	0	3	3	20	16
B	125	3	3	20	16
C	187.5	2	2	20	16
D	250	2	2	20	16
E	375	2	2	20	16

Parameters evaluated were growth rate, feed conversion, hematological and biochemical blood values, organ weight, post-mortem findings and histopathological assessment of sections of the heart, liver, spleen, kidneys, gonads, thyroids, adrenals, gizzard, eyes and brain of male and female turkeys of the 0 and 375 ppm lasalocid groups.

Continuous dietary administration of lasalocid at 125, 187.5, 250 and 375 ppm (i.e., maximum use level, 1.5X, 2X and 3X) to commercial turkeys, from one day old to 16 weeks old, resulted in the following changes in comparison with the control (untreated) group:

At week 16,0 male and female birds given lasalocid at 375 ppm had increased white blood cells and basophils together with increased glutamic-oxaloacetic transaminase (GOT) and phosphorus levels. Birds given lasalocid at 250 ppm also had raised glutamic-oxaloacetic transaminase (GOT) levels at week 16. These findings were not associated with any clinical observations.

Analysis of the organ weights showed heavier kidneys at week 12 and heavier brains at week 16 in birds given lasalocid at 250 and 375 ppm and lower adrenal weights in the 375 ppm birds at 16 weeks.

No treatment-related abnormalities were seen at post-mortem examination. A number of birds, distributed across all groups, were sacrificed as a result of leg abnormalities which included limb abduction, intertarsal joint deformity and/or enlargement, tibiotarsal dyschondroplasia, displaced tendons, etc.

These abnormalities were all considered to be of usual occurrence in intensively reared turkeys. A slight treatment-related trend may be linked to the greater body weights attained by the birds in the groups given lasalocid.

There were dose-related improvements in body weight in the birds given lasalocid. These were most marked in the male birds during the first 12 weeks of the study and in the female birds during the first 6 weeks of the study.

There were increases in feed consumption in the male birds during certain periods of the trial. In some cases these increases were associated with meaningful improvements in feed conversion ratios. There were no differences in feed consumption and feed conversion ratios in the female birds.

Treatment-related changes were not detected in the sections of heart, liver, spleen, kidneys, gonads, thyroids, adrenals, gizzard, eyes and brain examined from the control male and female turkeys and the highest lasalocid (375 ppm) male and female turkeys killed at termination.

It was concluded that continuous dietary administration of lasalocid at 125 ppm (maximum use level) to turkeys from day one to 16 weeks has no adverse treatment-related effects on growing turkeys.

Dr. Jeffrey Davidson, Tulare, California, conducted a safety study using 204 turkeys, equal numbers of each sex. The birds were placed into twelve floor pens and randomly assigned to treatments. Treatments were 0, 125 and 600 ppm lasalocid in the feed from day one through 8 weeks of age. Parameters measured

were body weight, feed consumption, feathering, leg soundness and blood clotting time. Birds fed the highest drug level had wet litter weeks three through eight. There were no gross or histo-pathological changes observed and there were no differences between treatments for performance, feathering, leg soundness and blood clotting time. Feed consumption was higher for the 125 ppm lasalocid group over control and the 600 ppm groups. Body weight was highest for the 125 ppm group over those of the controls and the highest level of lasalocid. Study treatments and observations (average of four replicates at 56 days) are shown in the following table.

Lasalocid ppm	Body Weight (kg)	Feed Conversion	Clotting Time (min)
0	2.50	2.12	1.7
125	2.64	2.10	1.6
600	2.26	1.82	1.3

Lasalocid is safe in young turkeys at the proposed maximum use level of 125 ppm and based on the results of this study appears safe even at 600 ppm in the diet. No adverse reactions, other than wet litter at the highest treatment level, were observed.
Dr. Larry McDougald, Athens, Georgia, conducted a controlled safety study in turkeys.
Two hundred sixty-four female and 204 male turkey poults (Nicholas commercial type broad-breasted white turkey breed) were fed in a floor-pen study from hatch to market age (15 weeks for female and 20 weeks for male birds). Male and female birds were housed in separate pens with 17 males and 22 females per pen. Three pens of males and three pens of females were assigned to each of four treatments. Turkeys were randomly assigned to pens and pens were randomly assigned to treatment.

The experimental treatments and associated responses were:

Lasalocid	Body Weight (kg)		Feed Conversion		Water Consuption (L/kg)	
ppm	Female 15 Wk	Male 20 Wk	Female	Male	Female	Male
0	7.1145	11.628	2.816	2.726	4.566	4.850
75	7.559	12.594	2.532	2.621	4.585	4.942
125	7.220	11.786	2.554	2.863	4.632	4.842

There were no untoward effects of feeding lasalocid at the highest recommended level.

B. Corroborative Study: Target Animal Safety

Dr. Jeffrey Davidson, Tulare, California, evaluated the safety of lasalocid when inadvertently fed to male and female turkeys of breeding age.
Day-old turkey poults were placed on unmedicated feed and raised to 24 weeks of age. Five (5) males were put into each of 12 pens with unmedicated feed, and 10 females were put into each of another 12 pens with unmedicated feed. Treatment groups were randomly assigned to pens of two blocks by sex.

Medicated feed was added to the pens for 10-day period with the following results:

	Unmedicated	Lasalocid	Lasalocid
Grams/ton	0	113	226
ppm	0	125	250
Average Weight Gain (Kg)	0.88	0.69	(-) 1.5
Feed Consumption (Kg)	127.45	122.25	91.35
Mortality	0	0	0

No adverse clinical/toxicological signs were seen in birds fed lasalocid at 113 g/ton. Birds fed lasalocid at 226 g/ton showed some decreased weight gain and apparent loss of appetite and were listless (four of six pens) for one to three days followed by a good recovery. No mortality occurred in any of the groups. It was concluded that inadvertent feeding of lasalocid to breeding age turkeys at the recommended dose of 113 g/ton (125 ppm) would have no significant clinical or toxicological effects.

VI. HUMAN FOOD SAFETY

A. Toxicity Tests and Safe Concentrations of Residues.

The Agency has established safe concentrations for total residues of lasalocid in turkey tissues as follows: 2.0 ppm in muscle, 6.0 ppm in liver, and 12 ppm in skin/fat. These values were determined using the procedure for setting safe concentrations for veterinary drugs published in the ***Federal Register*** of July 22, 1994 (Volume 59, page 27499).

The toxicity studies that support the safe concentrations listed above are summarized in the original Freedom of Information Summary for NADA 96-298.

B. Total Residue and Metabolism Studies.

The levels of lasalocid total residues in tissues of turkeys were established in Study Report No. HLR B-107'740 conducted by Dr. D. R. Hawkins at the Huntingdon Research Centre, England. In that investigation, sixteen turkeys (eight males and eight females) were administered 14C-labeled lasalocid at a concentration of 125 ppm (1X) in their feed for 14 days. The birds were sacrificed at eight hours (six birds) and at 24, 48, 72, 96, and 120 hours (two birds each) following the medication period. Samples of muscle, liver, kidney, abdominal fat, and skin/subcutaneous fat were collected and were assayed for total radioactivity.

The average total radioactivity values are listed below.

Total Radioactivity Expressed as ppm Lasalocid

W/D Time:	8 hrs	24 hrs	48 hrs	72 hrs	96 hrs	120 hrs
Muscle	0.30 ± .01	<0.02	<0.02	<0.02	<0.02	<0.02
Liver	3.38 ± .57	1.43	1.49	1.04	1.10	0.87
Kidney	0.43 ± .05	0.20	0.17	0.12	0.12	0.08
Fat Pad	0.16 ± .06	0.08	0.10	0.12	0.13	0.12
Skin/fat	0.30 ± .11	0.16	0.11	0.10	0.14	0.09

The patterns of metabolites present in the excreta and livers of turkeys treated with 14C-lasalocid in the study described above were determined and were compared with the patterns obtained with three toxicological test species, the dog, rat, and mouse. The metabolite profiling procedure involved sample extraction and fractionation, preparative layer chromatography, and high performance liquid chromatography analysis of the major fractions obtained.

The extraction of the 8-hour turkey livers in the total residue study showed that approximately 48% of the tissue radioactivity was extracted into methanol, while 52% of the radioactivity remained as bound residue in the liver tissue. The fractionation and chromatography of the extracted radioactivity indicated that lasalocid is extensively metabolized. The only major component identified in turkey liver was parent lasalocid, which represented 3.8% of the radioactiviy present. Unchanged lasalocid represented 18% of the radioactivity present in dog liver, 28% in mouse liver, and 32% in rat liver.

The patttern of lasalocid metabolites in turkey excreta was very similar to the pattern present in mouse feces. All of the components present in the turkey pattern were present in at least one of the toxicological species.

C. Bioavailability of the Turkey Liver Residue and Calculation of the Liver Total Residue of Human Food Safety Concern

A bioavailability study in the rat based on the Gallo-Torres model ("Methodology for the Determination of Bioavailability of Labeled Residues," H. E. Gallo-Torres, ***Journal of Toxicology and Environmental Health ,*** 2, 827-845 (1977)) was conducted at the Huntingdon Research Centre, Huntingdon, England (Report SCR 124893) in order to assess the relative bioavaliability of the lasalocid residue in turkey liver. Two groups of four rats each were used to measure the bioavailabilities of the incurred lasalocid residue in turkey liver and of parent 14C-lasalocid. The study yielded bioavailability values of 5.76% for the incurred liver residue and 43.9% for parent 14C-lasalocid. This equates to a relative bioavailability of 13% and allows an 87% discount of the bound lasalocid residue in turkey liver.

Relative Bioavailability = bioavailability of incurred residue / % bioavailability of parent drug = 5.76% / 43.9% = 0.131 or 13%

A value for the lasalocid turkey liver total residue of concern was determined by discounting a portion (87%) of the bound residue. This was done by first

calculating a total residue value for the turkey liver at 6 hours (zero) withdrawal. The residue study described in Part B used 8 hours as the zero withdrawal interval and extrapolation of the data in that study gave a value of 3.76 ppm to use as the turkey liver total residue value at 6 hours off medication. The bound portion of the 6 hour liver total residue represents 1.96 ppm. The extractable portion is the remaining 1.80 ppm, based on 48% extractability determined in the metabolite profiling work with the residues in liver (see Part B).

The lasalocid total residue of concern in turkey liver was calculated by adding the extractable residue (1.80 ppm) and 13% of the bound residue to give a final value of 2.05 ppm as shown in the following calculation.
Total Residue of Concern
= Extractable Residue + 0.13 X Bound Residue
= 1.80 ppm + 0.13 X 1.96 ppm
= 2.05 ppm

D. Withdrawal Time

The total residue and liver residue bioavailability data described above support a zero withdrawal for the use of lasalocid in turkeys. The total residue of concern in turkey liver has been calculated to be 2.05 ppm at zero withdrawal. That value is less than one-half the safe concentration of 6.0 ppm in turkey liver. In many cases, total residue studies are conducted at 1.5X (or greater) the intended dosing rate. When that is done, the tissue total residue must be less than the safe concentration to qualify for zero withdrawal, rather than one-half the safe concentration with the 1X dosing rate as in the case of this NADA.

E. Regulatory Methods

No regulatory method is required for the use of lasalocid in turkeys, because the residue data included in the NADA have met the requirements for zero withdrawal with waiver of the regulatory method. Those data have established that, at zero withdrawal, total redidue concentrations of concern in all edible tissues of turkeys treated at the intended dosage level of lasalocid are well below the safe concentraitons listed in Part A.

VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA 96-298 satisfy the requirements of section 512 of the Federal Food, Drug and Cosmetic Act (FFDCA). The data demonstrate that lasalocid sodium, when used at the proposed conditions, is safe and effective for the labeled indications. The approval provides for the use of lasalocid sodium in the range of 68 to 113 grams per ton (75 - 125 ppm) of feed, to prevent coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis*, and *E. adenoeides* in growing turkeys.

Proper use by non-veterinarians can be expected because poultry producers routinely use medicated feed containing an animal drug for the prevention of coccidiosis in growing turkeys. Directions are clearly written and there is reasonable certainty that the conditions of use, including mixing directions on the label, can and will be followed

by the producer. The agency has concluded that this product can be approved for over-the-counter use.

The data demonstrate that total residues of lasalocid sodium and its metabolites are well below the safe concentrations in all edible tissues at a zero withdrawal time. Consequently, the requirement for a regulatory method to monitor residues of the drug was waived.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food producing animals qualifies for THREE years of marketing exclusivity begining on the date of approval because the supplemental application contains reports of new clinical or field investigations essential to the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies only to the use of lasalocid sodium in growing turkeys, in the range of 68 to 113 grams per ton (75 - 125 ppm) of feed, to prevent coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis* , and *E. adenoeides*.

VIII. LABELING (ATTACHED)

1) Front Panel: AVATEC (TM) (lasalocid sodium) Type A medicated article 50 lbs (22.68 kg)
2) Back Panel: AVATEC (TM) (lasalocid sodium) Type A medicated article, Directions for Use
3) Blue Bird: Type C medicated feed labeling (Turkey Feed)

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.