I. GENERAL INFORMATION

A. File Number

NADA 140-998

B. Sponsor

SmithKline Beecham Animal Health
1600 Paoli Pike
West Chester, PA 19380

C. Proprietary Name

V-Max™

D. Established Name

virginiamycin

E. Pharmacological Category

Anticoccidial, antimicrobial, antiparasitic, etc.

F. Dosage Form

V-Max™ is supplied as a Type A Medicated Article containing 227 grams of virginiamycin activity per pound of medicated article.

G. Dispensing Status

Over the Counter (OTC)

H. Dosage Regimen

16 to 22.5 g/ton (90% dry matter basis) in Type C Medicated Feed to provide 100 to 340 mg/hd/day, for increased rate of weight gain. This is equivalent to 17.5 to 25 g/ton on a 100% dry matter basis.

11 to 16 g/ton (90% dry matter basis) in Type C Medicated Feed to provide 70 to 240 mg/hd/day, for improved feed efficiency. This is equivalent to 12 to 17.5 g/ton on a 100% dry matter basis.

13.5 to 16 g/ton (90% dry matter basis) in Type C Medicated Feed to provide 85 to 240 mg/hd/day, for reduction in the incidence of liver abscesses. This is equivalent to 15 to 17.5 g/ton on a 100% dry matter basis.

While the drug was tested on a 100% dry batter basis (g/ton) the drug intake is expressed on a 90% dry matter basis in order to provide labeling comparable with other rumen modifiers presently approved.

I. Route of Administration

Oral administration via the feed.

J. Indication

For increased rate of weight gain, for improved feed efficiency, and for reduction in the incidence of liver abscesses in cattle fed in confinement for slaughter.

II. EFFECTIVENESS

Pivotal Studies:

Four adequate and well-controlled clinical dose titration studies were conducted at three United States locations and one Canadian site. The names and locations of the investigators are presented below:

Dr. Mary Wray
Horton Feedlot/Research Center
Wellington, CO

Mr. Ray Grimson
Lakeside Research
Brooks, Alberta, CANADA

Dr. Donald Gill
Oklahoma State University
Stillwater, OK

Dr. Rodney Preston
Texas Tech University
Lubbock, TX

The purpose of the studies was to determine the effective dose levels of virginiamycin on rate of weight gain, feed efficiency and liver abscess incidence in feedlot cattle.

A total of 1520 cattle (1120 steers and 400 heifers) were used in the studies. At each of the four study locations, four treatment groups were replicated ten times in a randomized complete block design. Commercially available breeds were used, and animals were randomly assigned to pens based on their sex (only at Colorado and Alberta where both steers and heifers were used) and initial body weight (600-lbs). Treatments were randomly assigned to pens within each weight class. The pen was the experimental unit, there were 10 cattle per pen at two sites and 8 cattle per pen at the other two sites.

The treatment groups were 0, 10, 17.5 or 25 g/ton virginiamycin in complete feed (100% dry matter basis). The unmedicated group served as the control. Virginiamycin was supplied as Stafac(R) 500, the marketed formulation, and was administered orally via the feed as described on the label.

Management practices employed were consistent with commercial feedlot operations except that animals were fed once daily on an *ad libitum* basis. The diets were routinely assayed to assure that proper medication levels were maintained. The studies lasted 113-142 days; blocks of animals were removed at the study end when the investigator determined that desirable finish had been achieved.

Feed consumption, body weight and liver abscess scores were the primary parameters evaluated. Daily feed offered and periodic feed weighbacks by pen were recorded. Individual body weights were recorded approximately every 28 days. At study end, individual livers were scored 0, 1, 2 or 3, with 3 corresponding to the most severe abscess(es). Additionally, the test animals were observed throughout the studies for general health and for potential adverse drug effects, and at slaughter a variety of carcass parameters were recorded.

Average daily gain was calculated for each pen as the total body weight gain divided by the number of animals and the length of the interval (lbs/head/day). Feed efficiency was calculated for each pen as the total feed consumed (adjusted for removals and expressed on a dry matter basis) divided by the total weight gain. Liver abscess scores were condensed into either not condemned (score = 0) or condemned (score = 1, 2 or 3); the proportion was then subjected to the arcsin transformation for statistical analysis.

The results for the four individual trials and the pooled analysis are summarized in Tables 1, 2 and 3 for the Average Daily Gain, Feed Efficiency and Liver Abscess Incidence, respectively.

Table 1 Average Daily Gain (lbs/head/day)

Location	**Virginiamycin 0.0 g/ton**	**Virginiamycin 10.0 g/ton**	**Virginiamycin 17.5 g/ton**	**Virginiamycin 25.0 g/ton**
Colorado	2.526	2.634	2.693	2.684
Alberta	3.201	3.262	3.268	3.365
Oklahoma	3.469	3.435	3.484	3.544
Texas	2.731	2.676	2.785	2.825
Average over locations	2.982	3.002	3.058	3.105

Table 2 Feed Efficiency (Feed/Gain)

Location	**Virginiamycin 0.0 g/ton**	**Virginiamycin 10.0 g/ton**	**Virginiamycin 17.5 g/ton**	**Virginiamycin 25.0 g/ton**
Colorado	7.179	6.842	6.575	6.734
Alberta	6.582	6.425	6.391	6.394
Oklahoma	5.520	5.533	5.463	5.390
Texas	6.735	6.810	6.580	6.507
Average over locations	6.504	6.400	6.252	6.256

Table 3 Liver Abscess Incidence (% Condemned)

Location	**Virginiamycin 0.0 g/ton**	**Virginiamycin 10.0 g/ton**	**Virginiamycin 17.5 g/ton**	**Virginiamycin 25.0 g/ton**
Colorado	38.05	51.58	28.38	28.09
Alberta	58.47	65.96	52.19	38.40
Oklahoma	9.36	4.58	3.40	4.90
Texas	35.65	28.71	11.02	15.72
Average over locations	30.14	30.46	18.80	18.53

Average daily gain and feed efficiency for each individual trial was analyzed using analysis of variance (ANOVA) for a randomized complete block design. Then the Colorado and Alberta studies were combined and analyzed similarly, there was no significant difference in the response curves for steers and heifers ($p>0.25$) in this unweighted ANOVA (i.e., sex by treatment interaction was non-significant). Next, all four studies were combined. Bartlett's test revealed no significant heterogeneity of variance, so an unweighted ANOVA was performed. The overall treatment effects for both average daily gain and feed efficiency were significant ($p<0.01$ and $p<0.05$, respectively). The pooled data were fitted using polynomial regression and linear plateau models. For average daily gain, linear plateau model II (1,3) best described the data, and along with the method of nonoverlapping confidence intervals, determined that 17.5 to 25 g/ton was the effective dose range. For feed efficiency, linear plateau model III-2 (0,3) best described the data and determined that 12 to 17.5 g/ton was the effective dose range. Liver abscess incidence, calculated as the arcsin of the square root of the proportion condemned, was analyzed as described above. There was no significant difference in response for steers and heifers ($p>0.25$). In the unweighted ANOVA, the overall treatment effect was significant ($p<0.01$). Linear plateau model III-l (1,3) best described the data, 15 to 17.5 g/ton is the effective dose range.

No adverse reactions attributable to virginiamycin were observed.

III. TARGET ANIMAL SAFETY

Target Animal Safety of Virginiamycin in Beef Cattle

Study Number: VM-1042-87

Investigator:

Dr. Jeffrey Davidson
Health Management Services
3346 Avenue 248
Tulare, CA 93274

The study objective was to determine the potential toxicity of virginiamycin when fed to beef cattle for 112 consecutive days at 25, and 125 g/ton. Additionally, drug tolerance was tested by administering 625 g/ton for 28 days. This study was conducted in accordance with FDA GLP and CVM's Target Animal Safety Guidelines.

Thirty-six (18 males and 18 females) English bred cattle, 6-12 months of age and with an average initial body weight of 206 kg, were studied. The animals were randomly assigned by weight and sex to the following treatment groups: 0, 25, 75, 125, 625 g/ton. Two males and two females were assigned to the 625 g/ton group, and four males and four females were assigned to each of the other treatments. Virginiamycin was administered in the feed using the marketed formulation.

The cattle were inspected twice a day by the investigator for evidence of any clinical/toxicological abnormalities. A thorough physical exam, clinical pathology, urinalysis, blood and serum chemistries and fecal sample examination was performed on all of the animals during the acclimation period (5 days prior to the initiation of the study) and on days 0, 28, 56, 84 and 111 of the study. Daily feed consumption was recorded and body weights were measured approximately every 28 days. The animals were necropsied by a board certified pathologist by block on days 112, 113 and 114. Group five animals were necropsied on day 30.

Growth performance data were analyzed for each 28 day interval and cumulatively over the course of the 112 day trial. Overall data are presented in Table 4. Virginiamycin treatment groups (25, 75 and 125 g/ton) were compared to cattle receiving a non-medicated ration. Results indicate that cattle fed either 25 or 75 g/ton virginiamycin had average daily gains, feed intakes, and feed efficiency values which were similar to or better than control animals for each period and cumulatively over the 112 day trial. Cattle fed 125 g/ton virginiamycin showed reduced feed intake during all periods ($p<0.10$) and cumulatively over the course of the trial ($p<0.05$). Growth performance data for cattle in the 625 g/ton group during days 0-28 indicated that the medicated cattle had poorer average daily gain and feed intake ($p<0.05$) than control.

Table 4 Performance Over 112 Days

	Virginiamycin 0 g/ton	**Virginiamycin 25 g/ton**	**Virginiamycin 75 g/ton**	**Virginiamycin 125 g/ton**
Average Daily Gain	1.2079	1.3209	1.3544	1.1010
Average Daily Feed Intake	8.8722	9.0153	8.8292	8.0301
Average Daily Feed Efficiency	7.6741	7.0493	6.6543	7.6856

No significant abnormalities were noted in the general health, behavior or equilibrium of the animals, or in the various body systems which were examined by the investigator. No animals became ill, except for some transient diarrhea which occurred both in the control and the virginiamycin treatment groups. There was no mortality in the study. Statistical analyses were conducted for each of the clinical laboratory parameters (hematology, clinical chemistry, and urinalysis) using a repeated measures analysis with covariance adjustments for baseline (Day 0) values. Although significant differences were detected for some parameters, all mean results were within the range of expected variation and differences were biologically and toxicologically insignificant There were no lesions identified that were related to treatment with virginiamycin. No major adverse effects were observed in male or female cattle consuming 1X, 3X, 5X and 25X the recommended dosage level of

25 g/ton virginiamycin. The results of this study demonstrate the high level of safety for cattle fed at higher than the recommended dosages of virginiamycin.

Safety of Virginiamycin in the Diet of Beef Cattle

Study Number: V-1008-81

Investigator:

Dr. Louis Shor
SmithKline Beecham Animal Health
1600 Paoli Pike
West Chester, PA 19380

The objective of this non-pivotal study was to evaluate the safety of virginiamycin when fed to beef cattle for 23 weeks at 100 and 500 ppm. This study provides supportive data that virginiamycin is safe in feedlot steers.

Eighteen (9 males and 9 females) Hereford cattle, with an average initial body weight of 291 kg, were studied. The animals were randomly assigned by weight and sex to the following treatment groups: 0, 100, and 500 ppm. Virginiamycin was administered in the feed using the marketed formulation.

The animals were observed daily for evidence of any clinical/toxicological abnormalities. Physical examinations were performed on a weekly basis by the study director. The individual body weights were measured at four week intervals, except for the final weights which were taken after 23 weeks. Feed consumption was recorded for each period.

Growth performance data were analyzed for six time intervals: 0-4 weeks, 0-8 weeks, 0-12 weeks, 0-16 weeks, 0-20 weeks and 0-23 weeks. Virginiamycin treatment groups (100 and 500 ppm) were compared to cattle receiving a non-medicated ration. Results indicate that cattle fed either 100 or 500 ppm virginiamycin had average daily gains, feed intakes and feed efficiency values which were similar to control animals over the 23 week trial.

No significant abnormalities were noted in the general health, behavior or equilibrium of the animals, or in the various body systems which were examined by the investigator. No animals became ill except for some transient diarrhea which occurred in both the control and the virginiamycin treatment groups. There was no mortality in the study. Upon necropsy, there were no grossly visible lesions identified that were related to treatment with virginiamycin. Because of the normal clinical performance and appearance of the cattle and the absence of any remarkable gross pathology, histopathology was not conducted on the tissues.

No adverse effects were observed in male or female cattle consuming 4x and 20x the recommended dosage laevel of 25 g/ton virginiamycin. The results of this study support the high level of safety for cattlefed at higher than recommended dosages of virginiamycin.

IV. HUMAN FOOD SAFETY

A. Toxicity Studies

A complete summary of the toxicology studies is contained in the FOI for the supplemental approval for the use of virginiamycin in turkey feeds, under NADA 91-467.

B. Safe Concentrations for Virginiamycin Residues:

A six-month dog subchronic study was the most sensitive toxicity study with a no-observed-effect level (NOEL) of 25 mg/kg/day. With a 100 fold safety factor, the safe concentration for virginiamycin residues is:

$$\text{Virginiamycin Acceptable Daily Inntake (ADI)} = \frac{25\frac{\text{mg}}{\text{kg}}}{\frac{\text{day}}{\text{100 Fold Safety Factor}}}\text{(NOEL)} = \frac{0.25\frac{\text{mg}}{\text{kg}}}{\text{day}}$$

$$\text{100 Fold Safety Factor} = \text{ADI} \times \frac{\text{60 kg (wt of average human)}}{0.5\frac{\text{kg}}{\text{day}}\text{(daily meat consumption)}} = \frac{0.25\frac{\text{mg}}{\text{kg}}}{\text{day}} \times \frac{\text{60 kg}}{0.5\frac{\text{kg}}{\text{day}}} = 30 \text{ ppm}$$

This safe concentration for virginiamycin residue in muscle is applicable for cattle. Safe concentrations of virginiamycin residues in the edible tissues of cattle follow:

Tissue	Food Factor	Safe Concentration
Muscle	1	30 ppm
Liver	1/2	60 ppm
Kidney	1/3	90 ppm
Fat	1/4	120 ppm

C. Total Residue Depletion and Metabolism Studies Virginiamycin Equilibration in Tissues from Cattle Medicated at 0.34 mg/kg body weight/Day (activity basis)

Study Number: V-M-4044-87

Investigator:

Dr. David W. Gottschall
SmithKline Beecham Animal Health
1600 Paoli Pike
West Chester, PA 19380

Nine Hereford cattle (five steers and four heifers) weighing 230 - 300 kg were administered ^{14}C-virginiamycin medicated feed at 0.34 mg/kg body weight/day for 21, 28 or 35 days. This dosage is equivalent to 0.17 mg/kg body weight/day (weight basis) and 12.1 g/ton in complete feed. Following sacrifice at a practical

zero withdrawal (10-12 hours after removal of medicated feed), liver, kidney, muscle, subcutaneous fat, and renal fat were analyzed for total radioactive residues. The results are presented in Table 5. The liver contained the highest residue levels, although equilibration of residues was not attained during these medication periods.

Table 5 Total ^{14}C-Virginiamycin Radioactivity as Mean ppb Virginiamycin Equivalents

Days Treatment	Liver	Muscle[a]	Kidney
21	93±23	6.2	47±7
28	119±9	6.2±1.5	51±10
35	142±4	6.2	64±10

[a] The limit of measurement in muscle was 6.2 ppb.
*All subcutaneous fat samples assayed below the 27.7 ppb limit of measurement.
**All renal fat samples assayed below the 36.4 ppb limit of measurement.

Because a steady-state residue level was not reached, least squares linear regression was applied to the liver data to predict the maximum potential residue in liver after 150 days of medication followed by zero withdrawal. This is a conservative ('worst case') estimate because it assumes no equilibration will occur. Equilibration has been established in chickens and turkeys at 20 and 35 days, respectively. Since metabolism profiles are similar among chickens, turkeys, rats and cattle, it is likely that tissue equilibration in cattle will also occur. In fact, the cattle data at 21, 28 and 35 days indicate the beginning of the equilibration plateau at 35 days. Therefore, the predicted value of 619 ppb virginiamycin residues in cattle liver after 150 days of medication is a worst case estimate.

The residue data from this study were further adjusted to account for dosing at 12.1 g/ton. The maximum recommended dose in cattle is 25 g/ton. Therefore, the 619 ppb estimated total residue after 150 days of medication at 12.1 g/ton is equivalent to 1279 ppb after 150 days of medication at 25 g/ton, assuming that total virginiamycin residues increase in direct proportion to the administered dose. This assumption is supported by data obtained in the following study.

Excretion and Tissue Depletion Studies in Beef Cattle Treated with ^{14}C-Virginiamycin

Study Number: V-4027-84

Investigator:

D.R. Hawkins
Huntingdon Research Centre
Huntingdon, Cambridgeshire
ENGLAND

Twelve Friesan-Hereford cattle (eight males and four females) were administered non-radiolabelled virginiamycin for 14 days at 1 mg/kg body weight/day followed by ^{14}C-virginiamycin for 7 days at the same dose level. All doses were

administered in gelatin capsules. Three cattle were sacrificed at each of the following withdrawal times: 10, 24, 72, and 120 hours after the last dose. The results of the analyses for total residues are presented in Table 6.

Table 6 Total ^{14}C-Virginiamycin Radioactivity as Mean ppb Virginiamycin Equivalents

Hours Withdrawal	Liver	Kidney
10	348±105	399±273
24	386±79	210±95
72	281±99	200±105
120	237±10	112±15

*All fat samples assayed below the 250 ppb limit of measurement.
**All muscle samples assayed below the 50 ppb limit of measurement.

These data demonstrate that after seven days of dosing at 1 mg/kg body weight/day, cattle subjected to a practical zero withdrawal (10 hours after the last dose) have 228-424 ppb total virginiamycin residues in liver. In the previously described study, V-M-4044-87, least squares linear regression of the total liver residue data yields a predicted total liver residue value of 45.0 ppb for seven days of dosing at 0.17 mg/kg body weight/day at zero withdrawal. The difference in dose levels is approximately six-fold. Assuming a direct linear relationship between dose and tissue residue levels, the expected liver residue from study V-M-4044-87 a t a six-fold increased dose would be 45.0 x 6 = 270 ppb, which is within the range of observed values in study V-4027-84. The conservative estimate of 1279 ppb total virginiamycin residues in cattle liver at zero withdrawal is supported by these two studies. Comparative metabolism studies are summarized below.

Examination of Cattle Liver for the Presence of Virginiamycin Metabolites

Study Number: V-4045-87

Investigator:

Dr. David Gottschall
SmithKline Beecham Animal Health
1600 Paoli Pike
West Chester, PA 19380

Liver tissue was obtained from cattle treated with ^{14}C-virginiamycin for 35 days in study V-M-4044-87. Livers were extracted with organic solvents and aqueous buffer, and the extracts were characterized by HPLC and scintillation counting.

Approximately 30% of the total liver radioactivity was extractable with methanol (21.4%) and phosphate buffer (8.4%). The methanol extract was further separated into chloroform (11.8%) and methanol/water (8.4%) solubles. Most of the radioactivity remained as an intractable residue. The extractable radioactivity was further fractionated by HPLC analysis followed by scintillation counting of the collected fractions. The data indicated that no fraction contained greater than

4.9% (7 ppb) of the total residue. Additionally, virginiamycin fortified tissue extraction and analysis indicated that nearly 90% of the ^{14}C-virginiamycin was recoverable if present in the liver as the intact molecule. Virginiamycin is extensively metabolized in cattle and no single residue is present in sufficient quantity (i.e. >10% or 100 ppb) to be considered a major metabolite.

Examination of Virginiamycin Metabolites in Cattle Liver

Study Number: V-4031-85

Investigator:

Dr. David Gottschall
SmithKline Beecham Animal Health
1600 Paoli Pike
West Chester, PA 19380

Liver tissue was obtained from cattle treated with nonradiolabelled virginiamycin for 14 days followed by 7 days of ^{14}C-virginiamycin in study V-4027-84. Livers were extracted with organic solvents and aqueous buffer, and the extracts were characterized by HPLC and scintillation counting.

Approximately 37% of the total liver radioactivity was extractable with methanol (29.9%) and phosphate buffer (7.0%). The methanol extract was further separated into chloroform (12.0%) and methanol/water (22.3%) solubles. The majority of the radioactivity remained as intractable residue. The extractable radioactivity was further fractionated by HPLC analysis followed by scintillation counting of the collected fractions. The data indicated that no fraction contained greater than 6.4% (31 ppb) of the total residue. The results confirm the previous finding from study V-4045-87 that virginiamycin is extensively metabolized in cattle and no single residue is present in sufficient quantity to be considered a major metabolite.

Table 7 shows that partitioning of virginiamycin metabolites is similar in all species examined.

Table 7 Comparative Liver Residue Partitioning as Per Cent of Total Radioactivity

Species	**$HCCl_3$**	**$MeOH/H_2O$**	**Buffer**	**Pellet**
Turkey	7.2	10.7	8.6	43.5
Rat	4.0	10.8	8.3	65.2
Cattle	12.0	22.3	7.0	46.6
Cattle	11.8	8.4	8.4	74.9

Since none of the cattle metabolites would be expected to produce toxicity different than that demonstrated with virginiamycin, no further identification, characterization or toxicity testing of these minor metabolic products was required.

D. Withdrawal Period and Regulatory Method

Total residues of virginiamycin and its metabolites at zero withdrawal following 150 days of administration at 25 g/ton are conservatively estimated to be 1.279 ppm, well below the established safe concentration of 60 ppm, thus satisfying the residue chemistry requirements for zero withdrawal.

The residue level is so low compared to the calculated permitted residue level that a regulatory method to monitor residues is not required.

E. Antimicrobial Drugs for Long-term, Subtherapeutic Use in Animal Feeds

In accordance with 21 CFR 558.15, two studies were conducted to evaluate the effect of long-term, subtherapeutic use of virginiamycin in feedlot cattle on the development of antimicrobial resistance and on the *Salmonella* reservoir.

Effect of Virginiamycin on Tissue Levels, Antimicrobial Resistance and Shedding of *Salmonella typhimurium* from Cattle

Study Number: VM-6004-86

Investigator:

Dr. Diane Fagerberg
Colorado Animal Research Enterprises
Fort Collins, CO

Twenty-two calves were used in this study. After four weeks of acclimation, eighteen calves were fasted from food and water for 24 hours and then gavaged with *S. typhimurium* culture. Five days after the challenge, nine calves were fed virginiamycin in the feed at 250 mg/head/day and nine calves received non-medicated feed for eight weeks. The four non-challenged calves served as environmental controls, and the nine non-medicated calves served as the dose control. Fecal samples were collected prior to challenge, twice during the five-day postchallenge/pretreatment period, and 16 times during the next eight weeks. At study end, liver, spleen andintestinal lymph node samples were surgically excised from all challenged calves and the samples were tested for the presence of test salmonellae. *Salmonella* isolates were tested for susceptibility to a spectrum of antibiotics.

Virginiamycin fed to Salmonella-colonized beef calves did not significantly impact the overall mean Salmonella shedding, antimicrobial resistance or tissue sequestering.

Effect of Virginiamycin on the Incidence of Antimicrobial Resistance of Indigenous Fecal Coliforms from Cattle

Study Number: VM-6005-86

Investigator:

Dr. Diane Fagerberg
Colorado Animal Research Enterprises
Fort Collins, CO

Sixteen calves were used in this study. Eight calves were fed virginiamycin in the feed at 250 mg/head/day and eight calves received non-medicated feed for eight weeks. Fecal samples were obtained four times prior to treatment to establish baseline data, and eight times during the eight weeks of treatment. Coliform isolates were tested for susceptibility to a spectrum of antibiotics.

Continuous feeding of 250 mg/head/day virginiamycin for eight weeks to ruminating beef calves did not impact indigenous fecal coliform antimicrobial resistance.

V. AGENCY CONCLUSIONS

This original NADA satisfies the requirements of section 512(b) of the Federal Food, Drug and Cosmetic Act, and demonstrates that virginiamycin (V-Max®) when used under proposed conditions of use is safe and effective for the labeled indications. This production enhancing drug has been classified as "OTC." Its use does not raise any special safety concerns or require any diagnosis. Adequate directions for lay use have been included in the labeling. A tolerance for residues of virginiamycin in cattle tissue is not required.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals qualifies for three years of marketing exclusivity beginning on the date of approval because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

VI. ATTACHMENTS

V-Max™ Type A Medicated Article package label
Bluebird Type B Medicated Feed package label
Bluebird Type C Medicated Feed package label

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

Freedom of Information Office
Center for Veterinary Medicine, FDA
7500 Standish Place
Rockville, MD 20855

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.