Date of Approval: January 9, 2026

FREEDOM OF INFORMATION SUMMARY (FOI)

ORIGINAL NEW ANIMAL DRUG APPLICATION (NADA)

NADA 141-615

KBROVET®

(potassium bromide chewable tablets)

Dogs

KBROVET® (potassium bromide chewable tablets) are indicated for the control of seizures associated with idiopathic epilepsy in dogs.

Sponsored by:

Pegasus Laboratories, Inc.

Executive Summary

KBROVET® (potassium bromide chewable tablets) is approved for the control of seizures associated with idiopathic epilepsy in dogs. Potassium bromide, the active ingredient in KBROVET®, is an antiepileptic. KBROVET® is available in 250 or 500 mg tablets packaged in bottles containing 60 or 180 tablets. The total recommended daily dosage range for oral administration is 25 to 68 mg/kg (11 to 31 mg/lb) of body weight once daily.

Safety and Effectiveness

Three retrospective studies and a comprehensive literature review were used to establish the dose and demonstrate substantial evidence of effectiveness of KBROVET® for the control of seizures associated with idiopathic epilepsy in dogs.

The first effectiveness study determined the total daily oral dose range of potassium bromide (KBr) necessary to achieve serum bromide concentrations that are within 10% of the published therapeutic range (≥0.8 and ≤3.5 mg/mL) in dogs with idiopathic epilepsy. A total of 284 dogs in the database met the eligibility criteria for evaluation. The mean total daily oral dose was 46.4 (±21.9) mg/kg; the dose range with one standard deviation was 24.5 to 68.3 mg/kg.

The second effectiveness study was a retrospective evaluation of medical records of client-owned dogs treated with KBr monotherapy for management of canine idiopathic epilepsy. Dogs receiving other anti-epileptic medications were excluded. Seizure count, seizure event days, and seizure severity were assessed. Changes in seizure counts, seizure event days per month, and seizure severity scores were compared between the 30-day period before initial treatment with KBr and the 30-day period of steady state KBr dosing. Success in a treated dog was defined as a decrease by 50% or greater in seizure counts and seizure event days per month, and no worsening of seizure severity scores. Overall, of the 27 dogs included in the effectiveness analysis, 18 were considered treatment successes and 9 were considered treatment failures.

The third effectiveness study was a retrospective evaluation of medical records of client-owned dogs treated with KBr monotherapy for management of canine idiopathic epilepsy. Dogs receiving other anti-epileptic medications were excluded. Treatment success for an individual dog was defined as a 50% or greater reduction in seizure frequency measured during the 30-day period of steady state KBr dosing compared to the 30-day baseline period before initial treatment with KBr. Results of the study showed that compared to baseline, 40 out of 46 evaluable cases experienced at least a 50% reduction in seizure frequency.

The safety of KBROVET® is supported by a Public Master File containing data describing the target animal safety of potassium bromide and the safety information from the second and third effectiveness studies described above. In the Public Master File, reversible neurologic signs were the most consistently reported toxicosis and were generally associated with high serum bromide concentrations or concomitant use of potassium bromide treatment with other anti-epileptics. The most common adverse reactions seen in the retrospective studies were increased appetite and drinking, weight gain, vomiting, ataxia, and sedation.

Conclusions

Based on the information in the Public Master File and the data submitted by the sponsor for the approval of KBROVET®, the Food and Drug Administration (FDA) determined that the drug is safe and effective when used according to the label.

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I. GENERAL INFORMATION

A. File Number

NADA 141-615

B. Sponsor

Pegasus Laboratories, Inc.
8809 Ely Rd.
Pensacola, FL 32514

Drug Labeler Code: 055246

C. Proprietary Name

KBROVET®

D. Drug Product Established Name

potassium bromide chewable tablets

E. Pharmacological Category

Antiepileptic

F. Dosage Form

Chewable tablets

G. Amount of Active Ingredient

250 or 500 mg per tablet

H. How Supplied

Tablets are packaged in bottles containing 60 or 180 tablets.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The total recommended daily dosage range for oral administration is 25-68 mg/kg (11-31 mg/lb) of body weight. The dosage of KBROVET® should be adjusted based on monitoring of clinical response of the individual patient. KBROVET® may be dosed with or without food. Use of an initial loading dosage regimen may be considered on an individual patient basis, balancing the time required to achieve a therapeutic response while minimizing side effects.

K. Route of Administration

Oral

L. Species

Dogs

M. Indication

KBROVET® (potassium bromide chewable tablets) are indicated for the control of seizures associated with idiopathic epilepsy in dogs.

II. EFFECTIVENESS

One retrospective study was used to establish the dose of KBROVET® for the control of seizures associated with idiopathic epilepsy in dogs.

Substantial evidence of effectiveness was determined using two retrospective studies and a review of key scientific literature. Neither of the retrospective studies included a control group. Therefore, the effect observed in these studies was compared to a published placebo response rate in dogs with idiopathic epilepsy that was reported to be 29%.[1]

A. Dosage Characterization

The dose of KBROVET® administered orally once daily at 25 to 68 mg/kg (11 to 31 mg/lb) is based on a retrospective dose determination study.

Title: A Retrospective Evaluation of the Total Daily Oral Dose Range of Potassium Bromide to Achieve Serum Bromide Concentrations (Approaching Steady-State Conditions) that are within 10% of the Published Therapeutic Range in Dogs with Idiopathic Epilepsy. (Study No. PLI-CL017)

This retrospective evaluation was conducted to determine the total daily oral dose range of potassium bromide (KBr) necessary to achieve serum bromide concentrations (approaching steady-state conditions) that are within 10% of the published therapeutic range (≥0.8 and ≤3.5 mg/mL)[1] in dogs with idiopathic epilepsy. This evaluation did not involve prospective dosing or any assessment of patient response to treatment outcome. This evaluation included case records of client-owned dogs administered KBr in veterinary practice for control of seizures associated with canine idiopathic epilepsy. To be included as an evaluable case, the dog had to be administered only KBr to control the seizures associated with idiopathic epilepsy. A total of 284 dogs in the database met the eligibility criteria for evaluation. The mean total daily oral dose of KBr was 46.4 (±21.9) mg/kg. The mean dose duration was 187 (±177) days and the median dose duration was 120 days (45 to 1,260 days). The most common dosing interval was twice daily (65.1% of the dogs); the remaining dogs were dosed once daily. The mean serum bromide concentration (SBC) in the dogs included in the study was 1.51 (±0.5) mg/mL (range 0.8 to 3.1 mg/mL). The dosage range of 24.5 to 68.3 mg/kg was calculated from the sample mean ±1 standard deviation (SD) (46.4±21.9 mg/kg) which encompasses

[1] Muñana KR, Zhang D, Patterson EE. Placebo effect in canine epilepsy trials. J Vet Intern Med. 2010 Jan-Feb;24(1):166-70.

approximately 70% of the dosages administered that resulted in SBC from 0.8 to 3.1 mg/mL.

B. Substantial Evidence of Effectiveness

1. Pilot Study

Title: A Retrospective Pilot Study of the Effectiveness of Oral Potassium Bromide for the Control of Seizures Associated with Idiopathic Epilepsy in Dogs. Study No. (PLI-CL008)

Study Dates: January 2005 to August 2010

Study Location: Auburn, AL

Study Design:

Objective: To characterize the oral dose of KBr for the control of seizures in dogs with idiopathic epilepsy.

Study Animals: This was a retrospective study of medical records. To be included as an evaluable case, the dog had to have been administered only KBr to control seizures associated with idiopathic epilepsy. Dogs receiving other anti-epileptic medications were excluded. In order to meet the inclusion criteria of the study, the dog must have had a documented serum bromide concentration ≥0.8 and ≤3.5 mg/mL. The target goal was to identify an approximate total of 30 to 50 evaluable cases.

Experimental Design: Retrospective evaluation of medical records of client-owned dogs treated with KBr for the control of seizures associated with canine idiopathic epilepsy.

Drug Administration: Based on the pharmacokinetic similarities between immediate-release formulations of KBr, the study only included cases administered immediate-release oral KBr formulations. This included KBr formulated or compounded as a tablet, chewable tablet, capsule, liquid, or sprinkle granules. There were no specified dosage requirements in the retrospective study protocol.

Measurements and Observations: Seizure count, seizure event days, and seizure severity were assessed from study records. Changes in seizure counts, seizure event days per month, and seizure severity scores were tabulated for eligible cases, comparing the 30-day period before initial treatment with KBr and the 30-day period of steady state KBr dosing (the dog must have received the same total daily dose of KBr for a minimum of 60 days). Contrasts were calculated for each variable within each case by subtraction of pre-treatment and steady state treatment phase responses.

To be counted as a treatment success, individual cases were required to meet all three of the following criteria:

1. Seizure count success: Seizure count within an individual case was required to decrease by 50% or greater for the case to be classified as a seizure count

success (seizure count in the 30 days before treatment with KBr compared to seizure count in the 30 days at steady state KBr dosing).

2. Seizure event day count success: Seizure event days per month for an individual case was required to decrease by 50% or greater, compared to before treatment, for the case to be classified as a seizure event day count success.

3. Seizure severity score success: Severity score for an individual case was required to not increase during the 30 days of KBr treatment, compared to before treatment, for the case to be classified as a success for seizure severity.

Statistical Methods: Descriptive statistics were used to characterize effectiveness outcome variables, clinical findings, and adverse events.

Results: Case distribution, based on the included case medical records, spanned a 5.7-year period. An initial pool of 97 cases was identified for potential data acquisition. Of those 97 cases, 46 cases were excluded from evaluation due to a lack of medical record data, inadequate diagnosis, or lack of veterinarian response to further queries. The remaining 51 cases were further evaluated for study inclusion using the protocol-specified criteria. Of these 51 evaluable cases, 27 were determined as valid for safety and effectiveness data and 24 were determined to be valid for only safety data.

Case Distribution and Demographics: The 51 cases considered eligible for evaluation were from 18 different veterinary clinics. The majority of the 51 cases were male dogs (approximately 61%). Of the 51 cases, the mean age of onset of epilepsy was 2.1 years, the mean age of initiating KBr treatment was 2.4 years. Body weight data provided on 49 of the 51 cases showed a mean value of 23 kg, ranging approximately from 2 to 88 kg. The most represented breeds were mixed (approximately 24%), followed by Golden Retriever and Labrador Retrievers, each comprising approximately 10% of the 51 cases. Case distribution by geographic location included 9 states in the United States (US) with the majority from Texas and Maryland.

Dosage: The mean maintenance dose of the 51 cases evaluated for safety and effectiveness was 40.2 mg/kg/day, with a mean duration of dosing of 210 days. For the 27 cases comprising the effectiveness dataset, the mean maintenance dose was 37 mg/kg/day, with a mean duration of dosing of 286 days. Within the 27 cases evaluated for effectiveness, approximately 67% were dosed once daily and 33% were dosed twice daily. Most cases (63%) received KBr as a liquid dose form and approximately 31% received KBr in capsule form. Approximately 6% of the cases received KBr in tablet form.

Effectiveness: Of the 27 cases, 19 were defined as successes and 8 were defined as failures based on seizure count results. Eighteen were defined as successes and 9 were defined as failures based on seizure event day results. Seizure severity score decreased or did not change in 25 of the 27 cases evaluated for effectiveness. Overall, of the 27 dogs included in the effectiveness analysis, 18 were considered treatment successes and 9 were considered treatment failures.

Adverse Reactions: In the 51 cases included in the safety evaluation, increased appetite, weight gain, vomiting/regurgitation, and sedation were the most common adverse reactions documented in the 60-day period after start of KBr therapy.

Table II.1. Adverse Reactions Reported During Initial Dosing Phase (60 Day Period After Start of KBr Therapy; n=51)

Adverse Reaction	Number of Dogs with the Adverse Reaction
Increased Appetite	11
Weight Gain	8
Vomiting	5
Regurgitation	4
Sedation	3
Decreased Activity	3
Polydipsia	2
Ataxia	2
Polyuria	2
Weakness	2
Diarrhea	1
Disorientation	1
Partial Lack of Effectiveness	1
Petit Mal Epilepsy	1
Seizure	1
Tremor	1

Adverse reactions were also documented during the 30 days prior to serum bromide sample submission (Table II.2). At the time of sample submission, the dog must have received the same total daily dose of KBr for a minimum of 60 days (expected steady state dosing conditions).

Table II.2. Adverse Reactions Reported During Dosing Phase (30 Day Period of expected steady state dosing conditions; n=51)

Adverse Reaction	Number of Dogs with the Adverse Reaction
Weight Gain	7
Weakness	5
Ataxia	4
Increased Appetite	4
Polydipsia	3
Sedation	3
Diarrhea	2
Polyuria	2
Regurgitation	2
Vomiting	2
Decreased Appetite	1
Disorientation	1
Loose Stool	1
Panting	1
Tremors	1

Conclusions: The results of this retrospective study support the effectiveness of KBROVET®, at the total recommended oral daily dosage range of 25 to 68 mg/kg (11 to 31 mg/lb), for the control of seizures associated with idiopathic epilepsy. This study also supports the conclusion that KBr has an adequate safety profile in the target population.

2. Pivotal Study

Title: A Pivotal Retrospective Study of the Effectiveness of Oral Potassium Bromide for the Control of Seizures Associated with Idiopathic Epilepsy in Dogs. (Study No. PLI-CL013)

Study Dates: January 2016 to July 2024

Study Location: Auburn, AL

Study Design:

Objective: Retrospective study to characterize the effectiveness of immediate-release potassium bromide formulations administered orally for the control of seizures in dogs with idiopathic epilepsy.

Study Animals: This was a retrospective study of medical records. To be included as an evaluable case, the dog had to be administered only KBr to control the seizures associated with idiopathic epilepsy. Dogs receiving other anti-epileptic medications were excluded. To meet the inclusion criteria of the study, the dog must have had a serum bromide concentration ≥0.8 and ≤3.5 mg/mL.

Experimental Design: Retrospective evaluation of medical records of client-owned dogs treated with KBr for management of canine idiopathic epilepsy.

Drug Administration: Immediate-release oral KBr formulated or compounded as a tablet, chewable tablet, capsule, liquid, or sprinkle granules. There were no specified dosage requirements in the retrospective study protocol.

Measurements and Observations: The primary effectiveness analysis was based upon seizure incidence expressed as the number of seizures occurring during the 30-day baseline (prior to treatment with KBr) and the 30-day post-treatment evaluation periods. At the start of the 30-day post treatment period, the dog must have received the same total daily dose of KBr for a minimum of 60 days (expected steady state dosing conditions). Treatment success for an individual animal was defined as a 50% reduction in seizure frequency from baseline.

Statistical Methods: Descriptive statistics were used to characterize effectiveness outcome variables, clinical findings, and adverse events.

Results: A total of 46 eligible cases were identified and included in the final analysis dataset.

Case Distribution and Demographics: The year in which the post-treatment

evaluation period occurred ranged from 2010 to 2017, with most (91%) occurring between 2011 and 2016. Most dogs were female (52%) with a mean (SD) body weight of 20.2 (12.8) kg and a range of 3 to 44 kg. The median age at diagnosis of idiopathic epilepsy and start of KBr therapy were 3 (0.7, 5.3) and 3.2 (0.7, 5.6) years, respectively. Mixed breed (22%) and Labrador Retriever (11%) were the most common breeds.

Dosage: The median total daily maintenance dose of KBr was 33 (range 24.5 to 64) mg/kg/day and the median duration of therapy at the current dose was 81 (37 to 932) days. Loading doses were common, with 63% of patients receiving a mean SD loading dose of 115 (41) mg/kg/day administered over 2 to 7 days.

Effectiveness: Between baseline and the 30-day post treatment evaluation, 40 of 46 cases experienced at least a 50% reduction in seizure frequency.

Adverse Reactions: Clinical abnormalities were evaluated over a 60-day period that began 30 days before the 30-day post-treatment evaluation period (Table II.3). All clinical abnormalities were categorized using the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terminology convention. Overall, 26 patients experienced at least one clinical abnormality during the 60-day evaluation period.

Table II.3. Adverse Reactions Reported During 60-Day Period (n=46)

Adverse Reaction	Number of Dogs with the Adverse Reaction
Weight Gain	13
Vomiting	6
Sedation	3
Increased Appetite	2
Increased Drinking	2
Ataxia	1
Diarrhea	1
Flatulence	1
Frequent Urination	1
Lethargy	1
Neck Pain - Neurological	1
Ulcerative Dermatitis	1

Conclusions: The results of this retrospective study support the effectiveness of KBr for the control of seizures in dogs with idiopathic epilepsy at the total recommended oral daily dosage range of 25 to 68 mg/kg (11 to 31 mg/lb). The study also supports the conclusion that KBr has an adequate safety profile in the target population.

C. Key Scientific Literature to Support Use of Potassium Bromide in Veterinary Medicine

For nearly four decades, veterinary scientific literature has described KBr as monotherapy in the control of idiopathic epilepsy in dogs. In the American College of Veterinary Internal Medicine (ACVIM) Consensus Statement, potassium bromide

was recommended as a Level 1 antiepileptic drug - meaning that in blinded, randomized clinical trials the drug was effective in ≥50% of canine patients treated for at least 6 months.[2,3]

One manuscript evaluated the effectiveness of potassium bromide prospectively in dogs with idiopathic epilepsy.[4] In a double-blinded, randomized, parallel clinical trial, 46 anti-epileptic drug naïve dogs with naturally occurring epilepsy were evaluated with either phenobarbital or potassium bromide for seizure management. Diagnosis of epilepsy was made based on clinical pathology test results, medical history, and findings on physical and neurologic examinations. Forty-six patients were enrolled in the study: 21 in the phenobarbital group and 25 in the potassium bromide group. Groups did not differ significantly in terms of sex, body weight, or age. For potassium bromide-treated dogs, seizure number (P = 0.005) and severity (P = 0.001) were significantly decreased when compared to baseline. Also, seizure interval was significantly (P = 0.001) increased at study end, compared with baseline. Seizure duration decreased over time, although not significantly (P = 0.08). The percentage of dogs that did not have seizures (score of 0) when administered potassium bromide was 52% (12/23 dogs). The percentage of dogs in which seizures were successfully controlled was 65% (15/23 dogs). Seizure activity worsened at study end, compared with baseline, in 3 of 23 (13%) potassium bromide-treated dogs.

III. TARGET ANIMAL SAFETY

The safety of KBROVET® is supported by a Public Master File containing data describing the target animal safety of potassium bromide and the safety information from the two retrospective studies, Study No. PLI-CL008 and PLI-CL013, summarized above under Effectiveness.

A. Public Master File Reference – review of bromide safety

In September 2014, FDA announced availability of a Public Master File containing data describing the target animal safety of potassium bromide to support drug applications. This data is summarized in a published comprehensive review of published literature.[5]

Title: A systematic review of the safety of potassium bromide in dogs.

The objective of this systematic review was to critically evaluate and summarize the available information on the safety of potassium bromide in dogs. PubMed searches without date limitations were conducted with the terms "potassium bromide" and

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[2] Charalambous, M., Muñana, K., Patterson, E. E., Platt, S. R., & Volk, H. A. (2024). ACVIM Consensus Statement on the management of status epilepticus and cluster seizures in dogs and cats. *Journal of veterinary internal medicine*, *38*(1), 19-40.
[3] Bhatti, S. F., De Risio, L., Muñana, K., Penderis, J., Stein, V. M., Tipold, A., ... & Löscher, W. (2015). International Veterinary Epilepsy Task Force consensus proposal: medical treatment of canine epilepsy in Europe. *BMC veterinary research*, *11*(1), 176.
[4] Boothe, D. M., Dewey, C., & Carpenter, D. M. (2012). Comparison of phenobarbital with bromide as a first-choice antiepileptic drug for treatment of epilepsy in dogs. *Journal of the American Veterinary Medical Association*, *240*(9), 1073-1083.
[5] Baird-Heinz HE, Van Schoick AL, Pelsor FR, Ranivand L, Hungerford LL. A systematic review of the safety of potassium bromide in dogs. J Am Vet Med Assoc. 2012 Mar 15;240 (6):705-15. DOI: 10.2460/javma.240.6.705.

"sodium bromide" in December 2009 and October 2011. Additional articles were identified through examination of article reference lists and book chapters on seizures in dogs and pharmacology. Following this approach, the systematic review included 111 references reporting safety information relevant to potassium bromide published between 1938 and 2011.

Reversible neurologic signs were the most consistently reported toxicosis and were generally associated with adjunctive potassium bromide treatment or high serum bromide concentrations. Dermatologic and respiratory abnormalities were rare in dogs. Insufficient information was available to assess the effects of potassium bromide on behavior or to determine the incidence of vomiting, weight gain, polyphagia, pancreatitis, polyuria, polydipsia, or reproductive abnormalities associated with potassium bromide administration. Evidence suggested that administration of potassium bromide with food may alleviate gastrointestinal irritation and that monitoring for polyphagia, thyroid hormone abnormalities, and high serum bromide concentrations may be beneficial.

Results suggested that potassium bromide is not an appropriate choice for treatment of every dog with seizures and that veterinarians should tailor therapeutic regimens and clinical monitoring to each dog.

Based on the reviewed articles, the most common adverse drug events reported were found in the neurologic (including behavioral), gastrointestinal (including pancreatitis), reproductive, endocrine, dermatologic, and respiratory systems.

Polyuria and polydipsia were also present; however, they were not associated with a single body system.

Animals with decreased renal function may be predisposed to bromide toxicosis showing to a decreased ability to eliminate bromide as a result of reduced glomerular filtration rate.

Abrupt diet changes in dogs receiving KBr could either compromise seizure control or raise safety concerns.

Bromide toxicosis in dogs was most frequently associated with high serum bromide concentrations; however, authors have reported that toxicoses can be seen at low concentration in unusually sensitive dogs. One study found that most dogs that develop signs of toxicoses with bromide monotherapy had serum bromide concentrations in the range of 2.4 to 4 mg/mL, but this study also found that dogs were successfully treated without signs of toxicosis at serum concentrations as high as 4 to 4.8 mg/mL. Another publication reported clinical signs of toxicosis at serum bromide concentrations of approximately 4 mg/mL, but no signs of toxicoses at concentrations of 1.78 to 2.7 mg/mL. In a laboratory study, unspecified minimal signs of toxicosis were found in dogs administered a daily dose of 100 mg of NaBr/kg (45.5 mg/lb/d) for 6 weeks; mean serum concentration was 2.7 mg/mL.

It is important to monitor clinical signs of individual animals because effective and toxic serum bromide concentrations have been reported to differ between dogs and an overlap in toxic versus nontoxic serum concentrations has been demonstrated. In

fact, the use of clinical signs to judge appropriateness of treatment may be more important than monitoring serum bromide concentration alone.

Signs of more severe bromide intoxication were similar across species (humans, rats, mice, dogs, cattle, and horses) and included signs of depression, behavioral changes, ataxia, hind limb paresis, mydriasis, stupor, and coma.

Skin lesions were rarely reported in experimental overdose studies or in summaries of clinical cases of bromide intoxication in dogs. When reported, skin lesions in dogs were described as nonsuppurative white macules with scales or as pustular dermatitis. Development of sterile nodular panniculitis has been reported in patients receiving potassium bromide. This adverse event, which also appears in human medicine, appears to be dose dependent, most likely to happen after an increase in dose, and clinical signs appear to resolve upon withdrawal of the drug.

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

V. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to KBROVET®:

Not for human use.

Keep out of reach of children.

Contact a physician in case of accidental ingestion by humans.

VI. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR part 514. The data demonstrate that KBROVET®, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

A. Marketing Status

This product may be dispensed only by or on the order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional veterinary expertise is required to diagnose idiopathic epilepsy and to monitor safe use of the product, including treatment of any adverse reactions.

B. Exclusivity

KBROVET®, as approved in our approval letter, qualifies for FIVE years of marketing exclusivity beginning as of the date of our approval letter. This drug qualifies for exclusivity under section 512(c)(2)(F)(i) of the FD&C Act because this is the first time we are approving this active moiety in a new animal drug application submitted under

section 512(b)(1) of the FD&C Act. Any applicable exclusive marketing rights and exclusivity for this drug run concurrently.

C. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.