Date of Approval: March 16, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA)

NADA 141-406

NexGard®

(afoxolaner)

Chewable tablets

Dogs

This supplement provides for the addition of the indication for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

Sponsored by:

Boehringer Ingelheim Animal Health USA, Inc.

Executive Summary

NexGard® (afoxolaner) chewable tablet is approved for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

NexGard® is already approved to kill adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month. NexGard® is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

Safety and Effectiveness

Details of the studies conducted for the original approval of NexGard® and five supplemental approvals can be found in the FOI Summaries (NADA 141-406) dated September 14, 2013, April 1, 2014, May 15, 2014, February 23, 2015, July 13, 2018, and June 21, 2023, respectively.

The sponsor conducted two laboratory studies in young, healthy, intact male and female beagle dogs to demonstrate effectiveness against *A. maculatum*. In both studies, on Day 0, the dogs were either administered NexGard® or no treatment. Dogs were infested with approximately 50 unfed adult *A. maculatum* ticks at multiple timepoints, and live ticks were counted at 72 hours after treatment or each infestation.

In both studies, NexGard® was at least 97% effective at controlling *A. maculatum* infestations (reducing the number of live ticks) for one month, while dogs in the control group remained infested with live ticks at each tick count. NexGard® was also effective at treating *A. maculatum* infestations (increasing the number of dead ticks) for one month. Compared to dogs in the control group, treated dogs had a higher number of dead ticks. Self-limiting diarrhea was observed in one treated dog in one of the two studies and should be considered a possible drug-related adverse reaction.

The FOI Summary for the original approval of NexGard® (NADA 141-406), dated September 14, 2013, contains a summary of target animal safety studies for dogs.

Conclusions

Based on the data submitted by the sponsor for the approval of NexGard®, the Food and Drug Administration (FDA) determined that the drug is safe and effective when used according to the labeling.

Table of Contents

I. GENERAL INFORMATION

A. File Number

NADA 141-406

B. Sponsor

Boehringer Ingelheim Animal Health USA, Inc.
3239 Satellite Blvd.
Duluth, GA 30096

Drug Labeler Code: 000010

C. Proprietary Name

NexGard®

D. Drug Product Established Name

afoxolaner

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Chewable tablets

G. Amount of Active Ingredient

Each chewable contains 11.3 mg, 28.3 mg, 68 mg, or 136 mg of afoxolaner.

H. How Supplied

NexGard® is available in four sizes of beef-flavored soft chewables: 11.3, 28.3, 68 or 136 mg afoxolaner. Each chewable size is available in color-coded packages of 1, 3 or 6 beef-flavored chewables.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

NexGard® is given orally once a month, at the minimum dosage of 1.14 mg/lb (2.5 mg/kg).

Dosing Schedule:

Body Weight	Afoxolaner Per Chewable (mg)	Chewables Administered
4.0 to 10.0 lbs.	11.3	One
10.1 to 24.0 lbs.	28.3	One
24.1 to 60.0 lbs.	68	One
60.1 to 121.0 lbs.	136	One
Over 121.0 lbs.	Administer the appropriate combination of chewables	

K. Route of Administration

Oral

L. Species

Dogs

M. Indications

NexGard® kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month. NexGard® is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

N. Effect of Supplement

This supplement provides for the addition of the indication for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

II. EFFECTIVENESS

The effectiveness of NexGard® for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month, was demonstrated in two well-controlled laboratory studies described below.

A. Dosage Characterization

This supplemental approval does not change the previously approved dosage (2.5 mg/kg), given orally once a month. The FOI Summary for the original approval of NADA 141-406 dated September 14, 2013, contains dosage characterization information for dogs.

B. Substantial Evidence

1. Laboratory Dose Confirmation Study

Title: Efficacy of a Single Oral Treatment with NexGard® Against Induced Infestations of *Amblyomma maculatum* on Dogs. (Study No. 2023-3557)

Study Dates: May 9, 2024 to November 15, 2024

Study Location: Colbert, GA

Study Design:

Objective: To confirm the effectiveness of a single oral dose of NexGard® for the treatment and control of induced infestations of adult *Amblyomma maculatum* on dogs.

Study Animals: Twenty beagle dogs (7 males and 13 females), 8.0 to 12.6 months of age and weighing 6.9 to 11.7 kg.

Experimental Design: This study was a masked, negative controlled study using a completely randomized study design. Prior to allocation to treatment groups on Day -3, an initial tick infestation and count was conducted to evaluate susceptibility of each dog to induced infestation (host suitability). The dogs were randomized to treatment groups and infested with approximately 50 adult unfed *A. maculatum* ticks on Days -1, 14, and 28.

Tick counts were performed 72 hours after drug administration (Day 3) or tick infestation (Days 17 and 31). Ticks were not returned to the dog after counting. The study was conducted in accordance with Good Clinical Practice (GCP) guidelines.

Table II.1. Study 2023-3557; Treatment Groups

Treatment	Minimum Dose	Number and Sex of Dogs
Control	0 mg/kg	10 (4M, 6F)
NexGard®	2.5 mg/kg	10 (3M, 7F)

Drug Administration: On Day 0, the 10 dogs in the NexGard® treated group were administered one or more chewable tablets, at afoxolaner doses as close as possible to 2.5 mg/kg without under-dosing. Afoxolaner doses ranged from 2.5 to 3.1 mg/kg per dog. Dogs were fed prior to treatment. The 10 dogs in the control group received no treatment.

Measurements and Observations: The primary variable for effectiveness was the *A. maculatum* counts collected from the dogs. At each tick count, the ticks were removed, and the numbers of live and dead ticks were recorded. Physical examinations were conducted, and dogs were weighed on Day -7. Dogs were observed for health abnormalities at least once daily throughout the study, hourly for 6 hours after treatment, and at 8, 12, and 24 hours after treatment. Tick counts and health observations were conducted masked to treatment.

Statistical Methods: The experimental unit was the individual dog. For live tick counts at each time point, percent effectiveness of the treated group with respect to the control group was calculated using the formula [(C - T) / C] x 100, where C=the least squares (LS) mean of live tick counts for the control group and T=the LS mean of live tick counts for the treated group.

On each tick count day, untransformed live tick counts were analyzed using linear mixed models, including treatment as a fixed effect. The comparisons were tested using the two-sided 5% significance level. The total counts of dead ticks recovered from each dog and from its housing enclosure were used for calculation of arithmetic means by treatment group.

Effectiveness for the control indication was determined on the basis of the percent reduction (≥90%) in live tick counts in the treated group compared to the control group. Effectiveness for the treatment indication was determined on the basis of a numerically higher value of the arithmetic mean of dead ticks in the treated group compared to the control group.

Results: At each tick count, a minimum of 6 dogs in the control group had an adequate tick infestation, defined as a retention rate of at least 25% (i.e., ≥12 live ticks).

The NexGard® treated group had a ≥98.8% reduction in live *A. maculatum* tick counts at 72 hours (Table II.2) following treatment or infestation through Day 31. On all count days following drug administration, mean live tick counts between the NexGard® group and the control group were significantly different ($p<0.0001$). Dead ticks counted from the NexGard® treated group were higher compared to the control group at all post-treatment time points (Table II.3).

Table II.2. Study 2023-3557; *A. maculatum* Live Tick Counts and Percent Effectiveness 72 Hours After Administration or Infestation

Day of Tick Count	Control Group LS Mean	NexGard® Group LS Mean	Percent Effectiveness
3	40.6	0.2	99.5
17	38.5	0.0	100
31	34.7	0.4	98.8

Table II.3. Study 2023-3557; *A. maculatum* Dead Tick Counts 72 Hours After Administration or Infestation

Day of Tick Count	Control Group Arithmetic Mean	NexGard® Arithmetic Mean
3	0.2	37.4
17	0.8	25.0
31	0.9	20.6

Adverse Reactions: One dog in the NexGard® treated group had a single incidence of diarrhea noted five hours after treatment. The diarrhea resolved without treatment and was considered minor.

Conclusions: This study demonstrated the effectiveness of NexGard® for the control (reduced live ticks) and treatment (increased dead ticks) of *A. maculatum* ticks for one month when assessed 72 hours after drug administration or infestation. Diarrhea is considered a possible drug-related adverse reaction.

2. Laboratory Dose Confirmation Study

Title: Effectiveness of NexGard® for the Treatment and Control of *Amblyomma maculatum* on Dogs. (Study No. 2024-3687)

Study Dates: March 15, 2024 to June 4, 2025

Study Location: Bloemfontein, South Africa

Study Design:

Objective: To confirm the effectiveness of a single oral dose of NexGard® for the treatment and control of induced infestations of adult *Amblyomma maculatum* on dogs.

Study Animals: Twenty beagle dogs (13 males and 7 females), 13 to 77 months of age and weighing 14.6 to 20.0 kg.

Experimental Design: This study was a masked, negative controlled study using a randomized block study design. Prior to allocation to treatment groups on Day -3, an initial tick infestation and count was conducted to evaluate susceptibility of each dog to induced infestation (host suitability). The dogs were randomized to treatment groups within blocks based on the pre-treatment tick counts. The dogs were infested with approximately 50 adult unfed *A. maculatum* ticks on Days -2, 7, 14, 21, 28, and 35.

Tick counts were performed 72 hours after drug administration (Day 3) or tick infestation (Days 10, 17, 24, 31, and 38). Ticks were not returned to the dog after counting. The study was conducted in accordance with GCP guidelines.

Table II.4. Study 2024-3687; Treatment Groups

Treatment	Minimum Dose	Number and Sex of Dogs
Control	0 mg/kg	10 (6M, 4F)
NexGard®	2.5 mg/kg	10 (7M, 3F)

Drug Administration: On Day 0, the 10 dogs in the NexGard® treated group were administered 1 or more chewable tablets, at afoxolaner doses as close as possible to 2.5 mg/kg without under-dosing. Afoxolaner doses ranged from 2.5 to 2.8 mg/kg per dog. Dogs were fasted prior to treatment. The 10 dogs in the control group received no treatment.

Measurements and Observations: The primary variable for effectiveness was the *A. maculatum* counts collected from the dogs. At each tick count, the ticks were removed, and the numbers of live and dead ticks were recorded. Physical

examinations were conducted on Day -7, and dogs were weighed on Day -3. Dogs were observed for health abnormalities at least once daily throughout the study, and at 1, 3, 6, and 24 hours after treatment. Tick counts and health observations were conducted masked to treatment.

Statistical Methods: The experimental unit was the individual dog. For live tick counts at each time point, percent effectiveness of the treated group with respect to the control group was calculated using the formula [(C - T) / C] x 100, where C=the least squares (LS) mean of live tick counts for the control group and T=the LS mean of live tick counts for the treated group.

On each tick count day, untransformed live tick counts were analyzed using linear mixed models, including treatment as a fixed effect and block as a random effect. The comparisons were tested using the two-sided 5% significance level. The total counts of dead ticks recovered from each dog and from its housing enclosure were used for calculation of arithmetic means by treatment group.

Effectiveness for the control indication was determined on the basis of the percent reduction (≥90%) in live tick counts in the treated group compared to the control group. Effectiveness for the treatment indication was determined on the basis of a numerically higher value of the arithmetic mean of dead ticks in the treated group compared to the control group.

Results: At each tick count, a minimum of 6 dogs in the control group had an adequate tick infestation, defined as a retention rate of at least 25% (i.e., ≥12 live ticks).

The NexGard® treated group had a ≥94.6% reduction in live *A. maculatum* tick counts at 72 hours (Table II.5) following treatment or infestation through Day 38. On all count days following drug administration, mean live tick counts between the NexGard® group and the control group were significantly different ($p<0.0001$). Dead ticks counted from the NexGard® treated group were higher compared to the control group at all post-treatment time points (Table II.6).

Table II.5. Study 2024-3687; *A. maculatum* Live Tick Counts and Percent Effectiveness 72 Hours After Administration or Infestation

Day of Tick Count	Control Group LS Mean	NexGard® Group LS Mean	Percent Effectiveness
3	36.3	0.0	100
10	35.5	0.8	97.7
17	41.0	0.6	98.5
24	35.8	0.4	98.9
31	32.9	1.0	97.0
38	35.5	1.9	94.6

Table II.6. Study 2024-3687; *A. maculatum* Dead Tick Counts 72 Hours After Administration or Infestation

Day of Tick Count	Control Group Arithmetic Mean	NexGard® Arithmetic Mean
3	1.0	19.4
10	0.0	9.1
17	0.1	6.1
24	0.3	7.1
31	0.4	6.3
38	0.3	6.9

Adverse Reactions: No treatment-related adverse reactions were observed during the study.

Conclusions: This study demonstrated the effectiveness of NexGard® for the control (reduced live ticks) and treatment (increased dead ticks) of *A. maculatum* ticks for one month when assessed 72 hours after drug administration or infestation.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-406 dated September 14, 2013, contains target animal safety information for dogs.

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 NexGard®:

Not for use in humans. Keep this and all drugs out of the reach of children. In case of accidental ingestion, contact a physician immediately.

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 NexGard®, when used according to the label, is safe and effective for the effect of supplement in the General Information Section above.

A. Marketing Status

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional expertise is needed to monitor for and respond to adverse reactions.

B. Exclusivity

This supplemental approval for NexGard® qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the FD&C Act because the supplemental application included effectiveness studies. This exclusivity begins as of the date of our approval letter and only applies to the indication for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

C. Supplemental Applications

This supplement is a Category II supplement as defined in (21 CFR 514.106(b)(2)). This supplemental approval did not require a reevaluation of certain safety or effectiveness data in the application.

D. Patent Information

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