Fact Sheet for Veterinarians: Emergency Use Authorization of NexGard (afoxolaner) Chewables for New World Screwworm (NWS)

NexGard
(afoxolaner)
Chewables
For oral use in dogs

Original EUA Authorized Date: 02/18/2026

Emergency Use Authorization for NexGard (afoxolaner) chewables for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the approved product NexGard (afoxolaner) for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. NexGard is not approved for this use.

NexGard (afoxolaner) (NADA 141-406) is approved for other uses in dogs and puppies.[1]

Limitations of Authorized Use

NexGard (afoxolaner) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of NexGard (afoxolaner) under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Justification for Emergency Use of Animal Drugs for NWS

The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*); and

- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[2]

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances declared by the Secretary of HHS to justify emergency use authorization, including, among others, a determination that there is a public health emergency

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[1] 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), *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.

[2] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[3]

Criteria for issuing an EUA include:

- The biological agent can cause a serious or life-threatening disease or condition;
- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
    - the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and
    - the known and potential benefits of the product - when used to diagnose, prevent, or treat such disease or condition - outweigh the known and potential risks of the product; and
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[4]

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Product Description

Refer to the NexGard package insert for full **Product Description** information.

Dosage and Administration

NexGard is given orally at the minimum dosage of 1.14 mg/lb (2.5 mg/kg). NexGard should be used in conjunction with the mechanical removal of larvae (live and dead) remaining in the wound after treatment (see **Precautions**).

Dosing Schedule:

Body Weight	Afoxolaner Per Chewable (mg)	Chewables Administered
4 to 10 lbs.	11.3	One
10.1 to 24 lbs.	28.3	One
24.1 to 60 lbs.	68	One
60.1 to 121 lbs.	136	One
Over 121 lbs	Administer the appropriate combination of chewables	

NexGard can be administered with or without food.

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities)
[4] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

If suspected that any of the dose has been lost or if vomiting occurs within two hours of administration, redose with another full dose.

NexGard is not available in scored tablets. The effectiveness of the administration of less than full tablets has not been evaluated.

Risk-Benefit Consideration for Dogs on Other Isoxazolines:
If a dog is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering NexGard to dogs diagnosed with NWS larvae based on a risk-benefit assessment and the emergency nature of the treatment of NWS infestation.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that NexGard (afoxolaner) chewables may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, and when used under the conditions described in the authorization, the known and potential benefits of NexGard (afoxolaner) chewables outweigh the known and potential risks.

1. A study conducted in Brazil over a 13-month period by Cutolo et al.[5], evaluated 14 privately owned dogs naturally infested with *C. hominivorax* larvae. After diagnosis of myiasis by observation of larvae in a wound, all dogs were administered a single dose of NexGard (afoxolaner) orally at the recommended labelled dose for the approved indications (2.5 mg afoxolaner/kg body weight). The study did not include a control group. At 24 hours post-treatment, the lesions were evaluated, and all remaining larvae were mechanically removed from the wound. Expelled larvae were collected from the ground or around the dog. All larvae (expelled and mechanically removed) were dead 24 hours post-treatment. Larvicidal effectiveness was 100% at 24 hours post-treatment.

   Three dogs living in the same household developed *C. hominivorax* myiasis over a 41-day period. The first dog developed myiasis and was treated with NexGard (afoxolaner). The dog continued to live in the home environment while the wound was healing. Twenty-three days after the first dog was diagnosed and treated, the second dog was diagnosed with *C. hominivorax* myiasis, indicating active female fly activity in the environment. The second dog was treated with NexGard (afoxolaner). Both dogs were reexamined on the same day (33 days post-treatment for the first dog, 11 days post-treatment for the second dog). Neither dog had larval infestations. Eighteen days after the second dog was treated (41 days post-treatment for the first dog), the third dog was diagnosed with *C. hominivorax* myiasis and treated with NexGard (afoxolaner). Three days after the third dog was treated (44 days post-treatment for the first dog, 21 days post-treatment for the second dog), all the dogs were reexamined. No dog had larval infestations.

   One dog in the study presented with an extensive wound on the back of its neck that was reported to be repeatedly infested with *C. hominivorax* larvae. Twenty-nine days after

[5] Cutolo, A.A., Perier, N., Menz, I., Thyssen, P., Silva, F.O., & Beugnet, F. (2021). Effectiveness of afoxolaner (NexGard®) on the treatment of myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Veterinary parasitology, regional studies and reports*, 24, 100569.

diagnosis of myiasis and treatment with NexGard (afoxolaner), the lesion was almost completely healed, and no larval infestations were reported within that time.

No adverse events were recorded.

The study supports that NexGard may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis). More information is needed to evaluate the use of NexGard for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis).

2. A study conducted by Han et al.[6] evaluated 40 privately owned dogs with naturally occurring cutaneous myiasis; 8 dogs were treated with NexGard (range 2.7 to 6.8 mg/kg). All screwworms were presumed to be *Chrysomya bezziana* (Old World screwworm (OWS)), but morphological confirmation was not performed. Dogs were randomized to five treatment groups, eight dogs per group, and dosed orally at doses recommended by the manufacturer for treatment of their approved target parasite species. Dogs were evaluated hourly for 7 hours and again 24-hours post-treatment. Observations were recorded as no observed effect, partial paresis/death of some larvae and its expulsion, and complete death of all larvae. Dogs with live larvae present at 24 hours were then treated with topical organophosphates. The NexGard treatment group had live larvae 7 hours post-treatment but achieved complete larval kill in all dogs 24-hours post-treatment. The mean speed of onset was 4 hours and the mean time for complete eradication of larvae was 12 hours.

There are limitations of the data supporting the benefits of NexGard for treatment of infestations caused by NWS in dogs. The Cutolo et al. study was conducted in a limited population of 14 naturally infested dogs in Brazil. The lack of a control group confounds the ability to define a pure treatment effect. The Han et al. study was conducted with presumptive OWS infestations. The comparability of OWS and NWS is unknown.

The available clinical data supporting the effectiveness of NexGard against *C. hominivorax* larvae, along with the established safety profile, support the potential benefit of NexGard in the authorized patient population for treatment of infestations caused by NWS larvae.

Contraindications

There are no known contraindications for the use of NexGard.

Warnings

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.

Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

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[6] Han, H.S., Chen, C., Schievano, C. and Noli, C. (2018). The comparative efficacy of afoxolaner, spinosad, milbemycin, spinosad plus milbemycin, and nitenpyram for the treatment of canine cutaneous myiasis. *Veterinary dermatology*. 10.1111/vde.12548.

To obtain a Safety Data Sheet(s), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251 or www.nexgardforpets.com.

Precautions

Afoxolaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.

The safe use of NexGard in breeding, pregnant or lactating dogs has not been evaluated.

The safety of NexGard has not been evaluated in dogs less than 8 weeks of age or less than 4 lbs body weight.

Effective treatment of NWS myiasis includes removal of the larvae. Appropriate wound care, including surgical debridement as needed and pain management, should be implemented.[7]

Adverse Reactions

Refer to the package insert for full prescribing information, including **Animal Safety**, **Adverse Reactions** and **Post-Approval Experience**.

As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to NexGard (afoxolaner) chewables use under this EUA (1) by contacting Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251, (2) by downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or (3) contacting FDA at 1-888-FDA-VETS to request this form.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- The statement “NexGard (afoxolaner) use for NWS under an EUA” under the “**Adverse Event/Product Problem/Product Use Error”** heading
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes)
- Patient’s pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, lot number)

*Serious adverse events are defined as:

- Death

[7] Cutolo et al, Effectiveness of afoxolaner (NexGard®) on the treatment of myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. Vet Parasitol Reg Stud Rep. 2021:24:100569

- A life-threatening adverse event
- An event that causes an abortion, stillbirth, or infertility
- A congenital anomaly or birth defect in offspring of treated animals
- A prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions)
- An event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability)

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the mechanisms and including the information identified above for **SERIOUS ADVERSE EVENTS**.

Additional Information for Veterinarians

Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. Fact Sheets will be made available to veterinarians.

Veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs co-administered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

Veterinary facilities will maintain any health records for the authorized use in this Letter of Authorization for at least two years following the termination of the declaration or revocation of the authorization, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Boehringer Ingelheim Animal Health USA Inc., HHS, and FDA for inspection upon request.

Information for Client (e.g., Animal Owner)

The lifecycle for *C. hominivorax* is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. Dogs may become reinfested following treatment.

Clients should be advised that:

- Gloves should be worn if cleaning the wound, or the dog's bedding, or disposing of larvae.
- Dogs should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live larvae may exit the wound and be deposited on bedding or areas where the dog sits or lies after treatment.
- If expelled larvae are seen, owners should place the larvae in a sealed container with rubbing alcohol.

- If there is worsening of the wound, the owner should contact the veterinarian.

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.

Storage Information

Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).

Marketed by: Boehringer Ingelheim Animal Health USA Inc. Duluth, GA 30096

Rev. date 02/2026

NexGard®
(afoxolaner) Chewables

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description:
NexGard® (afoxolaner) is available in four sizes of beef-flavored, soft chewables for oral administration to dogs and puppies according to their weight. Each chewable is formulated to provide a minimum afoxolaner dosage of 1.14 mg/lb (2.5 mg/kg). Afoxolaner has the chemical composition 1-Naphthalenecarboxamide, 4-[5- [3-chloro-5-(trifluoromethyl)-phenyl]-4, 5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]-N-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl.

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), *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.

Dosage and Administration:
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 to 10 lbs.	11.3	One
10.1 to 24 lbs.	28.3	One
24.1 to 60 lbs.	68	One
60.1 to 121 lbs.	136	One
Over 121 lbs.	**Administer the appropriate combination of chewables**	

NexGard® can be administered with or without food. Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes to ensure that part of the dose is not lost or refused. If it is suspected that any of the dose has been lost or if vomiting occurs within two hours of administration, redose with another full dose. If a dose is missed, administer NexGard® and resume a monthly dosing schedule.

Flea Treatment and Prevention:
Treatment with NexGard® may begin at any time of the year. In areas where fleas are common year-round, monthly treatment with NexGard® should continue the entire year without interruption.

To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea control product.

Tick Treatment and Control:
Treatment with NexGard® may begin at any time of the year (see **Effectiveness**).

Contraindications:
There are no known contraindications for the use of NexGard®.

Warnings:
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. Keep NexGard® in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Precautions:
Afoxolaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.

The safe use of NexGard® in breeding, pregnant or lactating dogs has not been evaluated.

Adverse Reactions:
In a well-controlled US field study, which included a total of 333 households and 615 treated dogs (415 administered afoxolaner; 200 administered active control), no serious adverse reactions were observed with NexGard®.

Over the 90-day study period, all observations of potential adverse reactions were recorded. The most frequent reactions reported at an incidence of > 1% within any of the three months of observations are presented in the following table. The most frequently reported adverse reaction was vomiting. The occurrence of vomiting was generally self-limiting and of short duration and tended to decrease with subsequent doses in both groups. Five treated dogs experienced anorexia during the study, and two of those dogs experienced anorexia with the first dose but not subsequent doses.

Table 1: Dogs With Adverse Reactions.

	Treatment Group			
	Afoxolaner		Oral active control	
	N[1]	% (n=415)	N[2]	% (n=200)
Vomiting (with and without blood)	17	4.1	25	12.5
Dry/Flaky Skin	13	3.1	2	1.0
Diarrhea (with and without blood)	13	3.1	7	3.5
Lethargy	7	1.7	4	2.0
Anorexia	5	1.2	9	4.5

[1]Number of dogs in the afoxolaner treatment group with the identified abnormality.
[2]Number of dogs in the control group with the identified abnormality.

In the US field study, one dog with a history of seizures experienced a seizure on the same day after receiving the first dose and on the same day after receiving the second dose of NexGard®. This dog experienced a third seizure one week after receiving the third dose. The dog remained enrolled and completed the study. Another dog with a history of seizures had a seizure 19 days after the third dose of NexGard®. The dog remained enrolled and completed the study. A third dog with a history of seizures received NexGard® and experienced no seizures throughout the study.

In a second US field safety and effectiveness study, NexGard® was administered to 130 dogs with fleas. Adverse reactions included pruritus, diarrhea (with or without blood), vomiting, anorexia, and lethargy.

Post-Approval Experience (July 2018):
The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported for dogs are listed in decreasing order of reporting frequency for NexGard®:

Vomiting, pruritus, lethargy, diarrhea (with and without blood), anorexia, seizure, hyperactivity/restlessness, panting, erythema, ataxia, dermatitis (including rash, papules), allergic reactions (including hives, swelling), and tremors.

Contact Information:
For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251 or www.nexgardforpets.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

Mode of Action:
Afoxolaner is a member of the isoxazoline family, shown to bind at a binding site to inhibit insect and acarine ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. Prolonged afoxolaner-induced hyperexcitation results in uncontrolled activity of the central nervous system and death of insects and acarines. The selective toxicity of afoxolaner between insects and acarines and mammals may be inferred by the differential sensitivity of the insects and acarines' GABA receptors versus mammalian GABA receptors.

Effectiveness:
In a well-controlled laboratory study, NexGard® began to kill fleas four hours after initial administration and demonstrated >99% effectiveness at eight hours. In a separate well-controlled laboratory study, NexGard® demonstrated 100% effectiveness against adult fleas 24 hours post-infestation for 35 days, and was ≥93% effective at 12 hours post-infestation through Day 21, and on Day 35. On Day 28, NexGard® was 81.1% effective 12 hours post-infestation. Dogs in both the treated and control groups that were infested with fleas on Day -1 generated flea eggs at 12- and 24-hours post-treatment (0-11 eggs and 1-17 eggs in the NexGard® treated dogs, and 4-90 eggs and 0-118 eggs in the control dogs, at 12- and 24-hours, respectively). At subsequent evaluations post-infestation, fleas from dogs in the treated group were essentially unable to produce any eggs (0-1 eggs) while fleas from dogs in the control group continued to produce eggs (1-141 eggs).

In a 90-day US field study conducted in households with existing flea infestations of varying severity, the effectiveness of NexGard® against fleas on the Day 30, 60 and 90 visits compared with baseline was 98.0%, 99.7%, and 99.9%, respectively. In a second 90-day US field study, the effectiveness of NexGard® against fleas on the Day 30, 60 and 90 visits compared with baseline was 97.5%, 99.7%, and 99.9%, respectively. Dogs in the second study with signs of Flea Allergy Dermatitis (FAD) showed improvement in erythema, alopecia, papules, scales, crusts, and excoriation following treatment, as a direct result of eliminating fleas. Collectively, the data from these studies (two laboratory and two field) demonstrate that NexGard® kills fleas before they can lay eggs, thus preventing subsequent flea infestations after the start of treatment of existing flea infestations.

In well-controlled laboratory studies, NexGard® demonstrated >97% effectiveness against *Dermacentor variabilis*, >94% effectiveness against *Ixodes scapularis*, and >93% effectiveness against *Rhipicephalus sanguineus*, 48 hours post-infestation for 30 days. At 72 hours post-infestation, NexGard® demonstrated >97% effectiveness against *Amblyomma americanum* for 30 days and ≥98.5% effectiveness against *Haemaphysalis longicornis* for 31 days. In two separate, well-controlled laboratory studies, NexGard® was effective at preventing *Borrelia burgdorferi* infections after dogs were infested with *Ixodes scapularis* vector ticks 28 days post-treatment.

Animal Safety:
In a margin of safety study, NexGard® was administered orally to 8 to 9-week-old Beagle puppies at 1, 3, and 5 times the maximum exposure dose (6.3 mg/kg) for three treatments every 28 days, followed by three treatments every 14 days, for a total of six treatments. Dogs in the control group were sham-dosed. There were no clinically-relevant effects related to treatment on physical examination, body weight, food consumption, clinical pathology (hematology, clinical chemistries, or coagulation tests), gross pathology, histopathology or organ weights. Vomiting occurred throughout the study, with a similar incidence in the treated and control groups, including one dog in the 5x group that vomited four hours after treatment.

In two well-controlled field studies, NexGard® was used concomitantly with other medications, such as vaccines, anthelmintics, antibiotics (including topicals), steroids, NSAIDs, anesthetics, and antihistamines. No adverse reactions were observed from the concomitant use of NexGard® with other medications.

Storage Information:
Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).

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.

Approved by FDA under NADA # 141-406

Marketed by: Boehringer Ingelheim Animal Health USA Inc., Duluth, GA 30096
NEXGARD® is a registered trademark of Boehringer Ingelheim Animal Health France, used under license.

156090-003 Rev. 01/2023

Boehringer Ingelheim

U.S. FOOD & DRUG ADMINISTRATION

February 18, 2026

Boehringer Ingelheim Animal Health USA, Inc.
Attention: Tracy L. Robertson
Regulatory Affairs, Operations
3239 Satellite Blvd.
Duluth, GA 30096

Re: Emergency Use Authorization 006685

Dear Ms. Robertson:

This letter is in response to the request by Boehringer Ingelheim Animal Health USA, Inc. (Boehringer) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of NexGard (afoxolaner) chewables for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there issignificant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025 declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[1]

NexGard is an antiparasitic. NexGard kills fleas and is indicated under NADA 141-406 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 also indicated under NADA 141-406 for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks. NexGard is not approved for the treatment of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including data from published scientific literature, it is reasonable to believe that NexGard may be effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, as described in this authorization, and when used under the conditions described in this authorization, the known

[1] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

and potential benefits of NexGard outweigh the known and potential risks of such product for dogs of all ages and weights because NWS is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or less than 4 pounds in this authorization.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of NexGard for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of NexGard for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that NexGard may be effective in treating NWS and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of NexGard when used to treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative[2] to the emergency use of NexGard for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited as follows:

- NexGard, as covered by this authorization, will be used only for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies by a veterinarian by prescription; and

- The use of NexGard covered by this authorization must be in accordance with the authorized Fact Sheet.

[2] There are no approved alternatives for dogs and puppies under 8 weeks of age or weighing less than 3.3 pounds because the conditionally approved product is approved to treat NWS in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds. Additionally, there are no adequate approved alternative products containing a single active ingredient. The conditionally approved product contains multiple active ingredients, use of which may increase the likelihood of adverse events in dogs recently treated with a heartworm preventative or other antiparasitic drug in the same class as one of the ingredients in the conditionally approved product. Therefore, NexGard containing only a single active ingredient may minimize the potential for adverse events in these dogs.
[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

Product Description

NexGard is an antiparasitic. The authorized NexGard carton labeling is clearly marked for the approved indications and for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

Store at or below 30°C (86°F), excursions permitted up to 40°C (104°F).

NexGard is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians and others who may administer the product:

- Fact Sheet for Veterinarians: Emergency Use Authorization of NexGard (afoxolaner) Chewables for New World Screwworm (NWS)

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of NexGard, when used for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that NexGard may be effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that NexGard, as described in this authorization, meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, NexGard is authorized for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies as described in the this authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

A. Boehringer will ensure that the authorized NexGard, accompanied with the authorized Fact Sheet, is distributed to veterinary facilities[4] and veterinarians, or authorized distributor(s)[5], consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

B. Boehringer will ensure that if a sticker is used on the labeling, that the sticker contains a website address and QR code that link to the authorized Fact Sheet and that the sticker is placed in a blank space or does not obscure any important use or safety information.

C. Boehringer and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to veterinary facilities and veterinarians.

D. Boehringer and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, veterinary facilities, and veterinarians) involved in distributing or receiving authorized NexGard. Boehringer will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

E. Boehringer may request changes to this authorization, including to the authorized Fact Sheet for NexGard. Requests for changes should be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[6]

F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:

   Boehringer will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Boehringer will attempt to determine whether the use of NexGard was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Boehringer will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

   Submitted reports should state in the "Narrative of Adverse Event" field: "NexGard use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.

[4] Veterinary facilities include veterinary hospitals, veterinary clinics and other establishments providing veterinary care. If a veterinarian is not associated with a veterinary facility, the veterinarian then assumes the obligations of the veterinary facility.
[5] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Boehringer places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[6] Revisions that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, specified cGMPs, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

G. Through a process of inventory control, Boehringer and authorized distributor(s) will maintain records regarding distribution of the authorized NexGard (i.e., lot numbers, quantity, receiving site, receipt date).

H. Boehringer and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.

I. Boehringer will comply with all other FD&C Act requirements applicable to the approved product, NexGard, including, but not limited to, requirements related to registration and listing, drug quality, and manufacturing process, facilities, and equipment in accordance with the approved application[7], unless such requirement is specifically waived or modified for the authorized product in this authorization. Boehringer shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

Conditions of Authorization for Veterinary Facilities and Veterinarians

J. Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of this Letter of Authorization. Authorized Fact Sheets will be made available to veterinarians, and veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

K. Veterinary facilities and veterinarians receiving NexGard will track serious adverse events potentially related to NexGard use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting Boehringer at 1-888-637-4251, (2) downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or (3) contacting FDA at 1-888-FDA-VETS to request this form. Include the statement “NexGard use for NWS under an EUA” under the “Describe Adverse Event/Product Problem/Product Use Error” heading, followed by a detailed account of the adverse event.

L. Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs coadministered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

M. Veterinary facilities will maintain any records associated with this EUA for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS or FDA, whichever is sooner. Such records will be made available to Boehringer, HHS, and FDA for inspection upon request.

[7] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

Conditions of Authorization Related to Advertisements and other Promotional Descriptive Printed Matter

N. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of NexGard shall be consistent with the authorized Fact Sheet[8], and the terms set forth in this EUA, as well as comply with FD&C Act sections 502(a) and 502(n), and 21 CFR Part 202. Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

O. Boehringer and authorized distributor(s) may not imply that NexGard is FDA approved or conditionally approved for the authorized use by making statements such as "NexGard is safe and effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies". Boehringer and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of NexGard that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of NexGard shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- NexGard has not been approved for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies;
- NexGard has been authorized by FDA under an EUA for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies; and
- NexGard is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of NexGard under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revised or revoked sooner.

Q. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If FDA notifies Boehringer or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Boehringer

[8] If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the authorized Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

or authorized distributor(s) must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Boehringer or authorized distributor(s) to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheet

Electronic Signature Addendum for Submission ID

V-006685-A-0000-OT

Signing Authority (Role)	Letter Date
Timothy Schell (Center Director)	2/18/2026

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