1196 Hwy. 3 South · Northfield, MN 55057 · 888-215-1256 · www.aurorapharmaceutical.com

Date: February 19, 2024

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Suitability Petition for Afoxolaner Oral Solution 4.56% w/v**

Enclosed please find Suitability Petition submitted by Aurora Pharmaceutical, Inc., located at 1196 Hwy 3 South, Northfield, MN, 55057, under Section 512(n)(3) of the Federal Food Drug and Cosmetic Act to request an FDA permission to submit an abbreviated new animal drug application for generic animal drug **Afoxolaner Oral Solution 4.56% w/v**, that differs from reference listed new animal drug **Nexgard® (afoxolaner) Chewables (11.3 mg, 28.3 mg, 68 mg, and 136 mg afoxolaner per chewable)**, sponsored by Boehringer lngelheim Animal Health USA Inc. under NADA 141-406, in **dosage form**.

For additional information please contact:

Patrick Wadzinski, PharmD
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1196 Hwy 3 South
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19 Feb 2024

02/19/2024 09:34:42 am

Patrick Wadzinski, PharmD
Medical Affairs Pharmacist
Aurora Pharmaceutical, Inc.

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Afoxolaner Solution**

SUITABILITY PETITION

Action Requested:

Aurora Pharmaceutical Inc, located at 1196 Hwy 3 South, Northfield, MN, 55057, submits this petition under Section 512(n)(3) of the Federal Food Drug and Cosmetic Act to request FDA permission to file an abbreviated new animal drug application for generic animal drug **Afoxolaner Oral Solution 4.56% w/v**, that differs from the reference listed drug **Nexgard® (afoxolaner) Chewables (11.3 mg, 28.3 mg, 68 mg and 136 mg afoxolaner per chewable)**, Boehringer Ingelheim Animal Health USA Inc. under NADA 141-406 in that the **dosage form** is an oral liquid delivered in equivalent doses by an oral syringe and/or a calibrated unit dose device calibrated to deliver equivalent doses to the chewables.

Statement of Grounds:

The proposed generic copy will utilize the same active afoxolaner as RLNAD. The route of administration (oral) is the same. Recommended dosages are not changed. The justification for the proposed change of the dosage form and strength is the convenience of using a liquid, especially in dogs that are either allergic to chewable ingredients or dogs that find the chewable presentation unpalatable.

The RLNAD Nexgard® is approved as an oral chewable for dogs with an active afoxolaner content of 11.3 mg, 28.3 mg, 68 mg, and 136 mg soft chewables packaged into 1, 3, and 6 count packages. The monthly dosage of afoxolaner for oral administration in dogs is the minimum dosage of 1.14 mg/lb (2.5 mg/kg) of body weight.

The proposed generic dosage form is an oral solution of afoxolaner 4.56% w/v that will be packaged into multi-dose containers with calibrated oral dosing syringes for the 11.3 mg, 28.3 mg, 68 mg, and 136 mg doses as well as unit dose oral polyfoil tube ampules of 11.3 mg, 28.3 mg, 68 mg, and 136 mg. The monthly dosage of afoxolaner for oral administration in dogs is the minimum dosage of 1.14 mg/lb (2.5 mg/kg) of body weight.

To the extent of our knowledge, all excipients in the proposed generic formulation are already used in other approved oral products for dogs. This fact will be concurred with the FDA prior to bioequivalence study.

The following 7 unexpired patents are listed in the Green Book for the approved Nexgard® product, NADA 141-406:

1) Patent 7964204 expires on 12/28/2026, Aurora does not plan to market the proposed product prior to its expiration.
2) Patent 8231888 expires on 12/28/2026, Aurora does not plan to market the proposed product prior to its expiration.
3) Patent 8623875 expires on 6/10/2028, Aurora does not plan to market the proposed product prior to its expiration.
4) Patent 9095138 expires on 6/10/2028, Aurora does not plan to market the proposed product prior to its expiration.
5) Patent 8410153 expires on 6/20/2028, Aurora does not plan to market the proposed product prior to its expiration.
6) Patent 9233100 expires on 1/31/2033, Aurora asserts that its true solution formulation does not infringe this patent.
7) Patent 9931320 expires on 1/31/2033, Aurora asserts that its true solution formulation does not infringe this patent.

There is 1 unexpired exclusivity period for the Nexgard® product. It expires on 6/21/2026. Aurora does not plan to market the proposed product prior to its expiration.

A side-by-side comparison of Aurora's generic product Afoxolaner Oral Solution with reference listed new animal drug NexGard® (afoxolaner) Chewables is presented hereinafter.

Subject	**RLNAD**	**Aurora's generic**
Proprietary name (strengths)	NexGard® (afoxolaner) Chewables (11.3 mg, 28.3 mg, 68 mg and 136 mg)	Afoxolaner Oral Solution 4.56% w/v
Established name	Afoxolaner	Afoxolaner
Sponsor	Boehringer Ingelheim Animal Health USA Inc. Duluth, GA 30096	Aurora Pharmaceutical, Inc. 1196 Hwy 3 South, Northfield, MN 55057
Pharmacological category	Antiparasitic	Antiparasitic
Dosage form	Chewables, flavored	Solution
Active ingredient	Chewables containing 11.3 mg, 28.3 mg, 68 mg, or 136 mg of afoxolaner	Each mL of solution contains 45.6 mg of afoxolaner
How dispensed	Rx	Rx
Route of administration	Oral	Oral
Species/Class	Dog	Dog

Subject	RLNAD	Aurora's generic
Recommended dosage	Once a month at a minimum dosage of 1.14 mg/lb (2.5 mg/kg) body weight.	Once a month at a minimum dosage of 1.14 mg/lb (2.5 mg/kg) body weight.
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 *lxodes scapularis* vector ticks.	Afoxolaner Oral Solution 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 *lxodes scapularis* vector ticks.

The dosages will be the same for the proposed generic product as the referenced drug. A comparison of dosing is presented in the following table.

Dosing Schedule:

Body Weight	Afoxolaner Per Chewable (mg)	Chewables Administered	Equivalent Volume of 4.56 %w/v Solution administered (mL)
4 to 10 lbs.	11.3	One	0.25 mL
10.1 to 24 lbs.	28.3	One	0.62 mL
24.1 to 60 lbs.	68	One	1.5 mL
60.1 to 121 lbs.	136	One	3.0 mL
Over 121 lbs.	Administer the appropriate combination of chewables		Administer appropriate combination of calibrated liquid doses

Environmental Impact:

In accordance with 21 CFR 25.15, Aurora Pharmaceutical, Inc. claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR 25.30(h). We confirm that to our

knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

Economic Impact:
An economic impact analysis will be provided if requested after review of this petition.

Labeling:
General labeling information for the proposed generic Afoxolaner Solution 4.56% w/v will be essentially the same as the reference listed drug Nexgard® (Afoxolaner) Chewables labeling (attachment #1), except the changes in dosage form from chewable to solution, and information specific for the generic drug, namely proprietary name, how supplied, strength and administration instructions for the dosage form, palatability, "manufactured by" information, NDC#, label ID and revision date, and NADA# will be replaced by ANADA#.

Aurora Pharmaceutical, Inc. will include detailed dosing and administration directions in the labeling of the proposed generic product to ensure accurate dosing and prevent dosing errors. The specific language used in labeling will be agreed upon with CVM during the approval process.

Aurora Pharmaceutical, Inc. will include comprehensive user safety language on the labeling to ensure appropriate information regarding safety to humans who are handling, administering, and exposed to the proposed generic product. The specific language used in labeling will be agreed upon with CVM during the approval process.

Packaging:
Aurora Pharmaceutical, Inc. will supply the proposed generic product in container size(s) appropriate to the labeled indications and dosing directions. The specific container size(s) will be agreed upon with CVM during the approval process.

Certification:
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

If you have questions concerning this petition or require additional information, please, contact me by e-mail pwadzinski@aurorapharmaceutical.com or at tel. 507-645-3243.

Sincerely, SigPlus1 20 Feb 2024
02/20/2024 12:00:30 pm

Patrick Wadzinski, PharmD Date
Medical Affairs Pharmacist
Aurora Pharmaceutical, Inc.
1196 Hwy 3 South
Northfield, MN 55057

Attachment 1. Nexgard® (afoxolaner) Chewables, labeling by Boehringer Ingelheim Animal Health USA Inc. rev Oct 2023