FDA-2024-P-0889

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

Re: Suitability petition approved

Dear Dr. Wadzinski:

We approve your suitability petition (FDA 2024-P-0889) dated February 20, 2024. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic afoxolaner oral solution that differs in dosage form from the reference listed new animal drug (RLNAD). The RLNAD is NexGard® (afoxolaner) chewables, sponsored by Boehringer Ingelheim, under NADA 141-406. NexGard® is 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, weighting 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.

Your proposed changes from the RLNAD are changes that can be considered through a suitability petition, as defined under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). We find that the proposed changes do not require you to conduct investigations to show the safety and effectiveness of the generic new animal drug for its proposed intended uses. Therefore, we approve the petition under section 512(n)(3)(C) of the FD&C Act.

Approval of this suitability petition does not guarantee approval of the ANADA for your proposed generic new animal drug. We will make that determination after you have submitted your ANADA for our review.

When you submit your ANADA for your proposed generic new animal drug, you must identify the RLNAD referred to in this suitability petition and include a copy of this letter. We recommend that you request a presubmission conference, according to 21 CFR 514.5, to discuss the requirements and potential pathways for approval of the application.

A copy of this letter approving your petition will be placed on public display at www.regulations.gov with the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. If you have any questions, please contact Lauren (Gypsi) Feeney, DVM, Director, Division of Generic Animal Drugs, at Lauren.Feeney@fda.hhs.gov.

Sincerely,

Matthew A. Lucia -S

Digitally signed by Matthew A. Lucia -S
Date: 2024.05.02 14:32:05 -04'00'

Matthew Lucia, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

cc: HFV-170 (Petition File)
HFA-305 (Dockets Management Staff)