FDA-2019-P-0916

Schafer Veterinary Consultants, LLC
Attention: James H. Schafer, D.V.M.
US Agent for Felix Pharmaceuticals Private Limited
800 Helena Court
Fort Collins, CO 80524

Re: Request for approval of a suitability petition

Dear Dr. Schafer:

We approve your suitability petition (FDA-2019-P-0916) dated February 25, 2019. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic praziquantel compressed chewable tablet, which differs in dosage form from the reference listed new animal drug (RLNAD). The RLNAD is Droncit® (praziquantel tablets) for use in dogs and cats, sponsored by Bayer HealthCare LLC, Animal Health Division, under NADA 111-798. The RLNAD is approved for removal of the following:

- Canine cestodes: *Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus* and for the removal and control of *Echinococcus multilocularis*.
- Feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*.

The proposed generic new animal drug is a compressed chewable tablet containing 34 mg praziquantel for use in dogs and 23 mg praziquantel for use in cats. The RLNAD is a compressed tablet containing 34 mg praziquantel for use in dogs and 23 mg praziquantel for use in cats. The approved dosage schedule in dogs is:

- 5 lbs and under: ½ tablet
- 6-10 lbs: 1 tablet
- 11-15 lbs: 1 ½ tablets
- 16-30 lbs: 2 tablets
- 31-45 lbs: 3 tablets
- 46-60 lbs: 4 tablets
- Over 60 lbs: 5 tablets max

The approved dosage schedule in cats is:

- 4 lbs and under: ½ tablet
- 5-11 lbs: 1 tablet
- Over 11 lbs: 1 ½ tablets

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. 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 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 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 this application.

A copy of this letter approving your petition will be placed on public display at www.regulations.gov with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. If you have any questions, please contact Dr. Lauren (Gypsi) Feeney, Director, Division of Generic Animal Drugs, at (240) 402-0848 or Lauren.Feeney@fda.hhs.gov.

Sincerely,

Matthew A. Lucia -S

Digitally signed by Matthew A. Lucia -S
Date: 2019.05.15 08:24:58 -04'00'

Matthew A. Lucia, D.V.M.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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