FDA-2019-P-3109

Nobel Pharma LLC
Attention: David Nelson
President
4602 Domain Dr.
Menomonie, WI 54751

Re: Request for approval of a suitability petition

Dear Mr. Nelson:

We approve your suitability petition (FDA 2019-P-3109) dated June 24, 2019, as amended July 18, 2019. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic pyrantel pamoate and praziquantel chewable tablet that differs in dosage form from the reference listed new animal drug (RLNAD). The RLNAD is Virbantel® (pyrantel pamoate/praziquantel) Flavored Chewables, sponsored by Virbac AH, Inc., under NADA 141-261. Virbantel® is approved for the treatment and control of Roundworms (*Toxocara canis*, *Toxascaris leonina*), Hookworms (*Ancyclostoma caninum*, *Ancyclostoma braziliense*, and *Uncinaria stenocephala*), and Tapeworms (*Dipylidium caninum*, *Taenia pisiformis*) in dogs and puppies. The proposed strengths for the generic product and the approved strengths for the RLNAD are the same: 30 mg pyrantel pamoate/30 mg praziquantel (dogs weighing 6 -25 lbs) and 114 mg pyrantel pamoate/114 mg praziquantel (dogs greater than 25 lbs).

The proposed generic new animal drug is a chicken liver flavored, extruded, soft chewable tablet. The RLNAD is a compressed pork liver flavored chewable tablet. Please note that the labeling changes proposed under this petition were not evaluated for acceptability and will be reviewed under your application.

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 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 our review.

When you submit your ANADA for your proposed generic new animal drug, you must identify the reference listed new animal drug 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 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 at Lauren.Feeney@fda.hhs.gov.

Sincerely,

Matthew A. Lucia -S

Digitally signed by Matthew A. Lucia -S
Date: 2019.09.04 17:01:56 -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)