FDA-2022-P-3260

Noble Pharma LLC
Attention: Paul R. Hays
CEO
4602 Domain Dr.
Menomonie, WI 54751

Re: Suitability petition approved

Dear Mr. Hays:

We approve your suitability petition (FDA-2022-P-3260) dated December 19, 2022, as amended January 5, 2023. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic pimobendan soft-chewable (extruded) chicken-liver flavored tablet that differs in dosage form from the reference listed new animal drug (RLNAD), a compressed chewable tablet. The RLNAD is Vetmedin® (pimobendan) chewable tablet, sponsored by Boehringer Ingelheim Animal Health USA Inc., under NADA 141-273. Vetmedin® is approved for the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM). VETMEDIN is indicated for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by case basis.

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: 2023.03.14 18:03:13 -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)