FDA-2019-P-1566

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 deny your suitability petition (FDA-2019-P-1566) dated April 1, 2019. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic ivermectin and pyrantel (as the pamoate salt) chewable with an additional score. The RLNAD is Heartgard® Plus (ivermectin/pyrantel) Chewables, sponsored by Boehringer Ingelheim Animal Health USA Inc, under NADA 140-971. Heartgard® Plus is approved for use in dogs to prevent canine heartworm disease by eliminating the tissue state of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*).

The proposed generic new animal drug is a scored, poultry-flavored chewable. The RLNAD is a beef-flavored chewable. A change in flavoring and degree of hardness within a chewable dosage form are not changes which warrant pursuit of a suitability petition.

CVM recognizes the need for consistent scoring between a generic product and its RLNAD which aligns with CDER's Guidance for Industry: "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation." Your proposed change of an additional score to your generic product that differs from the RLNAD would require you to demonstrate safety and effectiveness for the generic new animal drug for its proposed intended uses. Therefore, we deny the petition under section 512(n)(3)(C) of the Federal Food, Drug, and Cosmetic Act.

If you wish to seek a reconsideration of our decision, you must follow the procedure in 21 CFR Part 10 and submit the request in the format outlined in section 10.22 no later than 30 days after the date of this letter to Division of Dockets Management, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must base your request solely on the information contained in your original petition (see 21 CFR 10.33(e)). If there is additional information, not included as part of your original petition that you would like us to consider, you should submit a new petition, including all the necessary information, under section 10.25(a) to the Division of Dockets Management.

In accordance with the reauthorization of the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA), effective October 1, 2018, all applications and submissions, addressed to the Office of New Animal Drug Evaluation (ONADE), need to be submitted to the Center for Veterinary Medicine (CVM) electronically using the eSubmitter tool. Paper submissions are no longer accepted by ONADE/CVM. For information about

submitting electronically to CVM, please see our website: https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm. If you have any questions regarding electronic submissions, email CVM's Electronic Submissions Support Team at cvmesubmitter@fda.hhs.gov.

A copy of this letter denying 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 or comments, please contact Dr. Lauren Feeney, Director, Division of Generic Animal Drugs, at (240) 402-0848 or at Lauren.Feeney@fda.hhs.gov.

Sincerely,

Elizabeth A. Rettie -S

Digitally signed by Elizabeth A. Rettie -S
Date: 2019.06.25 15:34:32 -04'00'

{see appended electronic signature page}

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)