DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 31 2014

FDA-2013-P-1512/CP1

PetaStrip, LLC
Attention: Alan Tempkins
Chief Executive Officer
605 Lincoln Road, Suite 301
Miami Beach, FL 33139

Re: Request for approval of a suitability petition

Dear Mr. Tempkins:

We deny your suitability petition (FDA-2013-P-1512/CP1) dated November 7, 2013. In the petition, you requested permission to submit an abbreviated new animal drug application (ANADA) for a proposed generic new animal drug that differs in dosage form from the reference listed new animal drug (RLNAD). The proposed generic new animal drug is an ivermectin impregnated soluble oral thin film with the same indications and dosage schedule approved for the RLNAD.

You identified the RLNAD as HEARTGUARD (ivermectin) Tablets, sponsored by Merial Ltd. under NADA 138-412; however, this NADA is for an ivermectin compressed tablet dosage form intended to be swallowed whole, not a soft chewable tablet. The correct RLNAD should be HEARTGUARD (ivermectin) Chewables for Dogs soft chewable tablets, sponsored by Merial Ltd under NADA 140-886. HEARTGUARD is approved for use in dogs 6 weeks or older to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection. The proposed strengths for the generic product and the approved strengths for the RLNAD are the same: 68 mcg, 136 mcg, and 272 mcg.

Your proposed change from the RLNAD is a change that can be considered through a suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the Act). However, we find that the proposed change requires you to conduct investigations to show the safety and effectiveness of the drug for its proposed intended uses. Therefore, we must deny the petition under section 512(n)(3)(C) of the Act.

If you wish to seek a reconsideration of our decision, you must follow the procedures found in 21 CFR Part 10 and submit the request in the format outlined in section 10.33 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.

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, please contact Dr. John K. Harshman, Director, Division of Generic Animal Drugs, at (240) 402-0845.

Sincerely,

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine