



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 2, 2013

Alan Tempkins, CEO
PetaStrip, LLC
605 Lincoln Road, Suite 301
Miami Beach, FL 33139

Dear Mr. Tempkins:

Your petition to the Food and Drug Administration requesting the Agency to grant permission to file an Abbreviated New Animal Drug Application (ANADA) for a generic new animal drug ivermectin soluble film which differs from the pioneer product, HEARTGARD Tablets, approved under NADA 138-412 (Merial Ltd.) for oral administration in dogs, was received by this office on 11/7/2013. It was assigned docket number FDA-2013-P-1512/CP1, and it was filed on 12/2/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)