SUITABILITY PETITION

Identification of Petitioner:

2013 NOV -7 A 11:26

PetaStrip, LLC
605 Lincoln Road, Suite 301
Miami Beach, Florida 33139

Citation:

PetaStrip, LLC submits this petition under section 512(n)(3) of the Federal Food, Drug and Cosmetic Act (the "Act") as a change in dosage form, a permitted variance from the pioneer product which can be considered through a Suitability Petition.

Action Requested:

PetaStrip, LLC requests permission for the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form than the pioneer product, i.e., soluble film (FDA Code 063; NDI Concept ID C42984).

Pioneer Product:	Heartguard® Tablets
Company:	Merial Limited
NADA #:	138-412
Active Ingredients:	ivermectin
Species:	Canine

The pioneer product is a chewable formulation. The proposed generic product will be a soluble film. The amount of active ingredients will be the same for both the pioneer product and the generic product. The dosage of the active ingredient per pound of body weight will be the same as well, and the proposed generic product is also intended for individual treatment, just like the pioneer product. The route of administration will also be the same as the pioneer product. The proposed generic product will be effective if in fact it is chewed or swallowed whole like the pioneer product. A copy of the pioneer labeling is enclosed. Both products will indicate that they may be offered by hand.

Statement of Grounds:

The active ingredient of Heartguard® is ivermectin formulated as a chewable tablet. The pioneer product is administered orally for the prevention of *Diofilaria immitis* for a period of one month (30 days) after infection and, as a result, prevents the development of the adult stage[1]. The use of an oral soluble film as an acceptable dosage form has been previously approved by the FDA

[1] 21 CFR 520.1193(d)(1)(ii)

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when the Suboxone® tablet (NDA #20-733) was approved under NDA#22-410, i.e, Suboxone® film.[2]

The proposed generic product will have the same indications, dosage, be administered orally, and will have the same therapeutic effect and contain the same cautions and warnings of the pioneer product. The pioneer product and the generic product will only differ in the dosage form as Heartguard® is in the form of a chewable given orally as compared to an oral soluble film. The generic label will be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as the different companies manufacturing the two products and the changes approved in this petition.

Safety and Effectiveness

The proposed generic drug product does not pose questions of safety or effectiveness because the uses, dose, route of administration of the proposed drug product are the same as that of the listed drug product. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments), to obtain approval, an ANADA applicant is not required to submit evidence establishing clinical safety and effectiveness of the drug product; instead, an ANADA relies on the FDA's previous finding that the pioneer product is safe and effective.[3]

Labeling:

The Sponsor acknowledges that there will be a definitive label review when the ANADA for the proposed generic product is submitted to the Center for Veterinary Medicine. The generic labeling will be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences. Attached is the pioneer labeling for Heartguard® for dogs, marked as Exhibit "A." The sections of the pioneer label that the proposed generic label will require revisions, subject to additional label review, are:

1. The "Administration" section will read as follows:

"Each PetaStrip comes in a sealed child-resistant foil pouch. Wait to open a PetaStrip until right before you use it. With dry hands, remove only one PetaStrip at a time. To open your PetaStrip foil pouch, carefully fold along the dotted line and tear down at slit or carefully cut with scissors along the arrow. Hold the film between two fingers and immediately place the PetaStrip on your dog's tongue where it dissolves in 4 to 20 seconds. If an additional PetaStrip is

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[2] Onsolis® (fentanyl buccal soluble film) is an oral transmucosal form of the potent opioid analgesic, fentanyl citrate, intended for application to the buccal mucosa, which has also been approved by the FDA. See also Zuplenz® (ondansetron) as another FDA accepted use of an oral soluble film dosage form.

[3] Suboxone® and Onsolis® required an REMS because it contained buprenorphine like morphine and other opioids, that has the potential for being abused and is subject to criminal diversion, and not because of the dosage form, i.e., soluble film. The abuse of buprenorphine poses a risk of overdose and death. This risk is increased with the abuse of buprenorphine and alcohol and other substances, especially benzodiazepines. The proposed generic product does contain any buprenorphine like morphine and other opioids; does not pose the same risks of being abused or criminal diversion; and has the same risks of the pioneer product.

necessary to achieve the prescribed dose, place the additional PetaStrip on the dog's tongue after the first PetaStrip has dissolved. Wash hands."

The remaining paragraphs of the Administration Section shall remain unchanged with the exception of the name of the product.

2. The "Acceptability" section will be deleted, because palatability will not be claimed. If the dog refuses the strip, the owner can force administration.

3. The "How Supplied" section will also be almost identical to the pioneer product, but the proposed generic product will read as follows:

   "PetaStrips are available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient cartons of 12 individually pouched strips."

Environmental Impact:

The action of submission and review of this Suitability Petition should not have an impact on the environment, as there is no residual of the product. Therefore, the Sponsor requests a categorical exclusion from the requirement to file an environmental assessment as provided under 21 CFR 25.30(h).

Bioavailability Requirements:

The Sponsor acknowledges that to be approved, the proposed generic product will, among other things, be required to meet bioavailability requirements under Section 512(n)(1)(E) of the Act. The Sponsor anticipates submitting protocols for review and concurrence to the Generic Animal Drugs Team prior to initiating bioequivalence studies for the proposed generic product.

Economic Impact Statement:

The Sponsor will provide an economic impact analysis if requested by the Commissioner.

Certification:

The undersigned certifies that no unfavorable information related to this petition has been withheld from the attached Suitability Petition.

11/5/13

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

Date:

FedEx Express **NEW Package US Airbill**

FedEx Tracking Number **8755 7581 2383**

SPH33

Form ID No. 0215

Recipient's Copy

1 From This portion can be removed for Recipient's records.

Date 11/6/13

FedEx Tracking Number 875575812383

Sender's Name Alan Tempkins Phone 305 398-7760

Company NEWMAN AND TEMPKINS ATTORNEY

Address 605 LINCOLN RD STE 301 Dept./Floor/Suite/Room

City MIAMI BEACH State FL ZIP 33139

2 Your Internal Billing Reference Pole Strip

3 To

Recipient's Name Division of Dockets Management From 301 8776560

Company Food & Drug Administration

Address 5630 Fishers Lane, Room 1061 Dept./Floor/Suite/Room

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address Use this line for the HOLD location address or for continuation of your shipping address.

City Rockville State MD ZIP 20852

HOLD Weekday FedEx location address REQUIRED. NOT available for FedEx First Overnight.

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2 or 3 Business Days

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Does this shipment contain dangerous goods? One box must be checked.

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Dangerous goods (including dry ice) cannot be shipped in FedEx packaging or placed in a FedEx Express Drop Box. ☐ Cargo Aircraft Only

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Total Packages 1 Total Weight ____ lbs. Credit Card Auth. ____

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