Health Canada Santé Canada

Canada License

NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS DIRECTORATE

Company Code: 39145
File Number: 562669
Submission Number: 562669

May 26, 2017

Mr. Yogesh Kumar Vyas
AYUSYA.NA INC
7895 Tranmere Drive, Suite 223
Mississauga, Ontario
Canada, L5S 1V9

Dear Mr. Yogesh Kumar Vyas:

Re: Product Licence Issuance - NPN 80077818
Non-Traditional - Soursop Juice (Liquid)

The Natural and Non-prescription Health Products Directorate (NNHPD) has concluded that the application is in compliance pursuant to section 7 of the *Natural Health Products Regulations* (NHPR). Please find enclosed a copy of the Product Licence hereby authorizing the sale of the product described therein.

Any labels used in the marketing of this product must reflect the information outlined on the product licence and must comply with the labelling requirements as per Part 5 of the NHPR. Please note that you are responsible for ensuring that advertising claims on the label do not contravene Section 9 of the Food and Drugs Act. Additional information on acceptable advertising claims can be obtained from the "Consumer Advertising Guidelines for Marketed Health Products (for Non-prescription Drugs including Natural Health Products)" at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum_e.html#a.1. Section 87 (Labelling and Packaging), specifies that you are responsible for ensuring the label text information is translated into French.

No person shall sell a natural health product unless it is manufactured, packaged, labelled, imported, distributed or stored in accordance with Part 3 - Good Manufacturing Practices of the NHPR or in accordance with equivalent requirements if the natural health product is imported. Section 44 of the NHPR outlines that each product available for sale in Canada must comply with the specifications submitted to Health Canada.

The submission of a signed Product Licence Application (PLA) form is regarded as an attestation acknowledging the licence holder's responsibility to meet the requirements set out in the NHPR and associated guidance documents relating to quality and Good Manufacturing Practices.

Product licence applications and post licensing changes based partially or completely on NNHPD monograph(s) are required to submit a Monograph Attestation Form. The submission of a signed Monograph Attestation form confirms that all conditions of the attestation are met, including the acceptance of any liabilities that may arise out of selling a product outside of the conditions of the attestation for which a product licence was issued based on this attestation.

As per the NHPR, you are responsible for providing the NNHPD with the Canadian site information prior to commencing the importation and/or sale of the natural health product. All information required is outlined in Part 1, Section 22 (1 & 2). If this information has not already been provided to NNHPD, please submit this information as a notification, as per section 12 (2) (b) of the NHPR.

Changes made in respect of a licensed product require the submission of an amendment, notification or a new product licence application as per sections 11, 12 and 13 of the NHPR.

If you notice any discrepancies concerning the information on the licence in comparison to the last submitted PLA form, please submit a notice entitled "Request for Correction to the Product Licence" indicating the corrections to be made, within 60 days after the day on which the product licence is issued, to NNHPD_DPSNSO@hc-sc.gc.ca. The File Number (provided at the top right corner of the title page) and Product Number must be quoted on all future correspondence regarding this product.

Yours truly,

Submission Management Division
Bureau of Product Review and Assessment
Natural and Non-prescription Health Products Directorate

encl.: Product Licence
c.c.: Chandrakant Patel

Canada

Health Canada / Santé Canada

Canada License

Product Licence
Licence de mise en marché

Product Number/*Numéro de produit*: 80077818
Brand Name/*Marque nominative*: Soursop Juice
Issued to/*Émise à:*
Name of licensee/*Nom du titulaire:*

AYUSYA.NA INC
7895 Tranmere Drive, Suite 223
Mississauga, Ontario, L5S 1V9
Canada

Authorized for the following/*Autorisé pour ce qui suit:*

Dosage form/*Forme posologique*: Liquid
Recommended route of administration/*Voie d'administration recommandée:*

Oral

Recommended dose/*Dose recommandée:*

Adults : Take 10ml Juice twice a day after lunch and dinner.
Additional Dosage Information: 1 teaspoon= 10ml

Recommended duration of use/*Durée d'utilisation recommandée:*

N/A

Recommended use or purpose/*Usage ou les fins recommandés:*

Source of antioxidants.

Risk Information/*Renseignements sur les risques:*

Known Adverse Reactions

If sleepiness, nausea, or sedation occurs; reduce the amount used.

Contra-Indications

Do not use if you are pregnant or breastfeeding. Do not use if you regularly consume graviola (soursop) fruit or tea or if you have atypical Parkinson's disease.

Cautions and Warnings

Consult a healthcare practitioner prior to use if you have low blood pressure, or if you are taking prescription anti-depressants, MAO inhibitors, antihypertensive or other cardiac depressant medications.

Medicinal Ingredients/*Ingrédients médicinaux:*

Proper Name Nom propre	Common Name Nom usuel	Quantity per Dosage Unit *Quantité par unité posologique*	Extract *Extrait*	Potency *Activité*	Source Material *Matière d'origine*
Annona muricata	Soursop	5 Grams	N/A	N/A	Fruit flesh

This licence is issued by the Minister of Health under the authority of section 7 of the Natural Health Products Regulations. Sale of the described natural health product, including any changes thereto pursuant to section 11 of the Regulations, is subject to the Food and Drugs Act and to the Natural Health Products Regulations.
Cette licence est émise par la ministre de la Santé en vertu de l'article 7 du Règlement sur les produits de santé naturels. La vente du produit de santé naturel décrit dans la présente, y compris toute modification afférente au sens de l'article 11 du Règlement, est assujettie à la Loi sur les aliments et drogues et au Règlement sur les produits de santé naturels.

Issued/émis le: 2017-05-26 Revised/Amended/Modifié le: N/A

Canada

Product Number/*Numéro de produit*: 80077818
Brand Name/*Marque nominative*: Soursop Juice

Director General/ *Int. Directeur général*
NHPD/*DPSN*