Product Licence
Licence de mise en marché

This licence is issued based on the attestations provided by the applicant in the respective product licence application, specifically/*Cette licence est émise en fonction des attestations fournies par le demandeur dans la demande de licence de mise en marché, spécifiquement*:

(a) that the information provided in the product licence application [proper name(s), common name(s), source material(s), route(s) of administration, dosage form(s), use(s) or purpose(s), dose(s), duration of use, risk information, etc.] respects the information contained in one NHPD monograph information/*que l'information fournie dans cette demande de licence de mise en marché [nom propre, nom usuel, matière d'origine, voie d'administration, forme posologique, usage ou fin, dose, durée d'utilisation, information sur les risques, etc.] respecte l'information contenue dans une monographies de la DPSN.*

(b) that the non-medicinal ingredients in the product do not exhibit pharmacological effects, do not have any effect contradictory to the product's recommended purpose, do not exceed the minimum concentration required for the formulation, do not adversely affect the bioavailability, pharmacological activity or safety of the medicinal ingredients, and that they are safe/*que les ingrédients non médicinaux contenus dans le produit n'entraînent pas d'effets pharmacologiques, n'ont pas d'effets contraires aux fins recommandées du produit, n'excèdent pas la concentration minimale requise pour la formulation, n'ont pas d'effets défavorables sur la biodisponibilité, l'activité pharmacologique ou l'innocuité des ingrédients médicinaux, et qu'ils sans danger;*

(c) that the label text is acceptable as per sections 86-94 of the Natural Health Products Regulations and the information on the label text is identical to the information provided in this product licence application/*que le texte figurant sur l'étiquette est acceptable, conformément aux sections 86 à 94 des Règlements sur les produits de santé naturels, et que l'information dans le texte figurant sur l'étiquette est identique à celle fournie dans la présente demande de licence de mise en marché;*

(d) that the natural health product's brand name(s) submitted in this product licence application is consistent with the product licence application, does not pose a risk to health and safety, and is not false and misleading/*que le nom de la marque nominative principale du produit de santé naturel soumis dans la présente demande de licence de mise en marché est conforme avec la demande de licence de mise en marché, qu'il ne pose pas de risque pour la santé et l'innocuité et qu'il n'est ni faux ni trompeur;*

(e) that the licence holder will comply with the conditions of this attestation. Upon receipt of this product licence, if the conditions of the attestation are not appropriately reflected on the product licence, the licence holder agrees to immediately notify the NHPD/*que le titulaire de la licence doit respecter les conditions de la présente attestation. Suite à la réception de cette licence de mise en marché, si les conditions de la présente attestation ne sont pas dûment prises en compte dans la licence de mise en marché, le titulaire de la licence accepte d'en aviser immédiatement la DPSN;*

(f) that operating outside of this attestation will result in being subject to compliance and enforcement, which could include additional requests for safety data pursuant to section 16 of the Natural Health Products Regulations, direction to stop sale pursuant to section 17 of the

Natural Health Products Regulations, or suspension or cancellation of this product licence pursuant to section 18 or 19 of the Natural Health Products Regulations; and/ *que si le titulaire de la licence opère en dehors de cette attestation, des mesures de conformité et d'application de la loi s'appliqueront, ce qui peut comprendre des demandes supplémentaires de données sur l'innocuité conformément à l'article 16 des Règlements sur les produits de santé naturels, la direction de cesser la vente conformément à l'article 17 des Règlements sur les produits de santé naturels ou la suspension ou l'annulation de la licence de mise en marché conformément à l'article 18 ou 19 des Règlements sur les produits de santé naturels;*

(g) that the licence holder accepts any liabilities that may arise out of selling a product outside of the conditions of this attestation for which a product licence was issued based on this attestation/ *que le titulaire de la licence accepte toute responsabilité qui pourrait découler de la vente d'un produit en dehors des conditions de cette attestation pour laquelle une licence de mise en marché a été délivrée en fonction de cette attestation.*

Product Number/*Numéro de produit*: 80099934
Brand Name/*Marque nominative*: Gel Hand Sanitizer
Other Brand Name(s)/*Autre(s) marques(s) nominatives(s)*:

Issued to/*Émise à:*
Name of licensee/*Nom du titulaire*:
Spirit of York Distillery Co.
12 Trinity Street
Toronto, Ontario
M5A 3C4
Canada

Authorized for the following/*Autorisé pour ce qui suit*:
Dosage form/*Forme posologique*: Gel
Recommended route of administration/*Voie d'administration recommandée*: Topical

Authorised according to the NHPD monograph(s) to which the applicant attested/*Tel qu'autorisé dans la(les) monographie(s) de la DPSN à laquelle(auxquelles) le demandeur a attesté*:
Recommended dose/*Dose recommandée*
Recommended duration of use/*Durée d'utilisation recommandée*
Recommended use or purpose/*Usage ou les fins recommandés*
Risk Information/*Renseignements sur les risques*

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*
Ethyl alcohol	Ethyl alcohol	*As authorized in the NHPD monograph(s) to which the applicant attested*			

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*: 2020-05-08	Revised/Amended/*Modifié le*: N.A./S.O.

Director General / Directeur général
NNHPD/DPSNSO

Canada

Health Canada Santé Canada

NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS DIRECTORATE

Company Code: 48381
File Number: 627742
Submission Number: 627742

May 8, 2020

Mr. Germain Guitor
Spirit of York Distillery Co.
12 Trinity Street
Toronto, Ontario
Canada, M5A 3C4

Dear Mr. Germain Guitor:

Re: Product Licence Issuance - NPN 80099934
Compendial - Gel Hand Sanitizer (Gel)

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