Health Canada Santé Canada

APPLICATION FOR INTERNATIONAL TRADE CERTIFICATE FOR NATURAL HEALTH PRODUCTS

NATURAL HEALTH PRODUCTS DIRECTORATE

April 2010
Version 1.0

Canada

“Our mission is to help the people of Canada maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

Natural Health Products Directorate

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FOREWORD

The current approach to the issuance of international trade certificate for natural health products has been in place since 2004. The policy was developed to enable applicants to continue to export their products while they became in compliance with the *Natural Health Products Regulations*. Five years after its implementation, the Natural Health Products Directorate (NHPD) conducted a review of its current approach to the issuance of international trade certificates for natural health products (NHPs). As a result of this review the policy on international trade certificates has been revised. These changes will ensure Canada's global reputation as a leader in the regulation of NHPs, and as an exporter of NHPs that are safe, effective and of high quality.

The Guidance on the Application for International Trade Certificates has been revised to reflect these changes.

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1. PURPOSE

This document is intended to provide a general description of the Natural Health Products Directorate's (NHPD) International Trade Certificates (ITCs) for natural health products (NHPs). This document describes the requirements to be met for the issuance and the procedure to apply for an ITC.

2. BACKGROUND

Firms exporting NHPs from Canada are often asked by foreign customers or foreign regulatory authorities to supply a certification relating to products subject to the *Natural Health Products Regulations* (NHPR). This ITC is a document prepared by NHPD containing information about a product's or site's regulatory status in Canada.

In many cases, foreign regulatory authorities are seeking official assurance that NHPs exported to their countries can be marketed in Canada and meet the NHPR. Review of an ITC may be required as part of the process to register or export a product into another country.

An ITC contains information about a product's or site's regulatory and marketing status in Canada. The issuance of an ITC does not suggest or imply that Health Canada sanctions any specific product, only that the product and/or site has met the regulatory requirements in Canada. It is the responsibility of the product licence holder to market a safe and properly labelled product. The issuance of this document does not preclude Health Canada from taking regulatory action against a product or a site, if such action is warranted.

An ITC for NHPs is not required under the NHPR but is voluntarily issued by NHPD as a service to industry to facilitate the export process for the Canadian natural health product industry.

3. SCOPE

An ITC is issued for natural health products authorized for sale in Canada and for licensed sites that are compliant with Good Manufacturing Practices of the *Natural Health Products Regulations*. ITCs are not issued for human and veterinary drugs or foods. To obtain export certificates for these products please contact the Health Products and Food Branch Inspectorate (HPFBI) or the Canadian Food Inspection Agency (CFIA).

4. INTERNATIONAL TRADE CERTIFICATES

4.1 Issuance of International Trade Certificates

The Natural Health Products Directorate (NHPD) issues two types of International Trade Certificates:

1. **International Trade Certificate for Natural Health Products (NHPs):** is issued for those NHPs which possess a valid product licence (PL) in the form of a Natural Product Number (NPN), or a Drug Identification Number for Homeopathic Medicines (DIN-HM), and are manufactured, packaged and labelled in sites that possess a valid site licence (SL). This ITC is country and product specific, naming one product and one country as the country of destination.

2. **International Trade Certificate of Good Manufacturing Practices (GMP) Compliance**: is issued for sites which possess a valid SL. The certificate will clearly indicate the date of issuance, the authorized activities and the expiry date of the SL. This certificate is not product specific. All or any of the sites on the SL that are located in Canada may be listed on the certificate. The International Trade Certificate of GMP Compliance does not name the country of destination.

4.2 Refusal to Issue International Trade Certificates

NHPD will not issue ITCs for the following reasons:

- When the Canadian site does not possess a valid site licence and/or is not GMP compliant;
- When the NHP for which the application is made has not received market authorization in Canada;
- When Section 37 of the *Food and Drugs Act* (FDA) is invoked[1];
- When the product, site or applicant in question is subject to any current compliance and enforcement action; and
- When the application is incomplete.

[1] Section 37 exempts certain drugs from the application of the FDA: 37. (1) "This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation"and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner."

4.3 Application Process

An applicant may request an ITC by downloading and completing the templates found on the Health Canada website at: **www.healthcanada.gc.ca/nhp**. Instructions on completing these certificates can also be found on the website. Completed ITC templates must be submitted by mail to the following address:

Submission Management Division
Qualicum Tower A
2936 Baseline Rd.
AL 3302B
Ottawa, Ontario
K1A 0K9
(for courier K2H 1B3)

Applicants must include a completed shipping form (waybill Purolator, Fedex, Loomis, UPS, Dicom, etc.) and courier envelope with each request. Should a shipping form not be included with the request, the document will be returned to the applicant via regular mail.

Once received, the NHPD will review the information contained in the certificates to ensure accuracy. If the information is complete, the certificates will be signed, stamped and returned to the applicant by mail or courier. If the information is inaccurate or incomplete the application will be returned to the applicant.

Please note that the applicant must be located in Canada. If the applicant is not the PL holder, a letter from the PL holder authorizing the applicant to export the product must accompany the application. Only the SL holder may request an International Trade Certificate of GMP Compliance.

4.4 Request for Stamping

If documents such as NHPD-issued documents (e.g., PL-SL) indicated on the ITC, need to be stamped by NHPD, the applicant must complete a “Request for Stamping Form” (Appendix D) and:

- Have the completed form sworn before a Commissioner for Taking Oaths (Public Notary) and

The “Request for Stamping Form” should accompany the completed ITC template. Certificate holders, who were unaware of an importing authority’s stamping requirements at the time of applying for an ITC must:

- Provide the certificate number and security label number of their ITC when subsequently submitting a request for stamping.

If the applicant is not the product licence holder:

- A letter of authorization from the PL holder must accompany the “Request for Stamping Form”.
- With a letter of authorization from the PL holder on file, the “Request for Stamping Form” can be signed and notarized by the non PL holding applicant.

If the PL holder is not the manufacturer of the product in question:

- Both a letter of authorization from the PL holder and a “Request for Stamping Form” signed and notarized by the manufacturer are required to ensure that all information on file at NHPD is accurate and up-to-date.

The NHPD will stamp:

- NHPD-issued documents (e.g. PL, SL, etc.) for authentication purposes;
- documents related to the product formulation of a licensed product (e.g. testing methods, product specifications, certificates of analysis, organic certificates, etc.);
- documents provided as part of the evidence package of an approved site licence (e.g. stability, standing operating procedure (SOP), stability record, etc.);
- documents attesting to packaging and labelling compliance of a licensed product (e.g. packaging and labelling specifications, test result for packaging and labelling, labelling information, etc.); and
- documents demonstrating the sale of an authorized product in Canada (e.g Sale Invoices).

The NHPD will <u>not</u> stamp:

- any documents pertaining to sites or products for which a PL and/or SL have not been issued;
- packaging and labels;
- Quality Assurance Reports, if said reports are being used as proof of GMP compliance (SL holder should seek a certificate of GMP compliance);
- raw material information;
- documents attesting to the fact that products and/or sites have received third party certification (e.g. ISO certification, advertising pre-clearance, etc.); and
- commercial information or any other type of document conveying information which is not on file at NHPD.

4.5 Fees

NHPD currently issues ITCs as a voluntary service however a fee system may be developed for these certificates, in the near future.

5. DEFINITIONS

Canadian Food Inspection Agency (CFIA):
The Canadian Food Inspection Agency delivers all federal inspection services related to food, animal health, and plant protection. For further information please visit their website at: **http://www.inspection.gc.ca**

Certificate of Pharmaceutical Product (CPP):
A certificate issued by the Inspectorate establishing the status of the pharmaceutical, biological, radiopharmaceutical or veterinary product listed and the GMP status of the fabricator of the product.

Commissioner for Taking Oaths:
Person authorized to swear affidavits.

Good Manufacturing Practices:
Measures to ensure an overall effective approach to product quality control and risk management. They apply to places, people, processes and products with respect to which activities are being conducted. Please refer to Part 3 of the *Natural Health Products Regulations* and the Good Manufacturing Practices Guidance Document found at**: www.healthcanada.gc.ca/nhp**

Health Products and Food Branch Inspectorate (HPFBI):
The Health Products and Food Branch Inspectorate of Health Canada is responsible for the management of inspection, investigation, monitoring activities and enforcement strategies related to the fabrication, packaging/labelling, testing, importation, distribution and wholesaling of regulated health products for human and veterinary use.

International Trade Certificate for Natural Health Products:
A certificate which speaks to the regulatory and marketing status of the natural health product and site in Canada.

International Trade Certificate of Good Manufacturing Practices Compliance:
A certificate issued by NHPD which speaks to the regulatory and compliance status of the specified site(s) authorized to conduct the following activities with respect to NHPs: manufacturing, packaging, labeling or importing.

Natural Health Product (NHP):
A substance set out in Schedule 1 of the *Natural Health Products Regulations* or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

b) restoring or correcting organic functions in humans; or
c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Schedule 1
Included Natural Health Product Substances

1)	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2)	An extract or isolate of substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3)	Any of the following vitamins: biotin folate niacin pantothenic acid riboflavin thiamine vitamin A vitamin B_6 vitamin B_{12} vitamin C vitamin D vitamin E
4)	An amino acid
5)	An essential fatty acid
6)	A synthetic duplicate of a substance described in any of items 2 to 5
7)	A mineral
8)	A probiotic

Schedule 2
Excluded Natural Health Product Substances

1)	A substance set out in Schedule C to the *Act*
2)	A substance set out in Schedule D to the *Act*, except for the following: (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3)	A substance regulated under the *Tobacco Act*
4)	A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5)	A substance that is administered by puncturing the dermis
6)	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

Natural Product Number (NPN) / Drug Identification Number for Homeopathic Medicines (DIN-HM):
An eight (8) digit numerical code assigned to each natural health product and homeopathic medicine authorized to be marketed under the *Natural Health Products Regulations.*

Regulatory Authority:
A government agency or other government entity that has a legal right to control the use or sale of NHPs within that country and that may take enforcement action to ensure that NHPs marketed within its jurisdiction comply with legal requirements.

Site:
A place of or for an activity specified under the *Natural Health Products Regulations*.

Site licence number:
A number issued by Health Canada's Natural Health Products Directorate based on the requirements set out in the *Natural Health Products Regulations* as proof of authorization to conduct specified activities at the listed locations.

WHO:
The World Health Organization.

6. FREQUENTLY ASKED QUESTIONS CONCERNING INTERNATIONAL TRADE CERTIFICATES

Q.1 What is an International Trade Certificate?

A certificate which speaks to the regulatory and marketing status of the natural health product or site in Canada.

Q.2 Do I require an International Trade Certificate to export a natural health product from Canada?

No. This certificate is not required under the *Natural Health Products Regulations*. The Natural Health Products Directorate voluntarily issues these certificates upon request to facilitate the export process for Canadian manufacturers as a service to industry, when requested.

Q.3 Does issuance of an international trade certificate indicate that Health Canada sanctions a product or a site?

No. An international trade certificate contains information on the regulatory status of the product and site in Canada. The issuance of a certificate does not suggest or imply that Health Canada sanctions any specific product or site.

Q.4 Who can apply for an International Trade Certificate?

The applicant must be located in Canada. If the applicant is not also the product licence holder or have legal responsibility for the product, a letter from the product licence holder or person / company with legal responsibility for the product authorizing the applicant to export the product must accompany the application. Only the SL holder may request an International Trade Certificate of GMP Compliance.

Q.5 What is the difference between an Export Certificate completed under Section 37 of the *Food and Drugs Act* and an International Trade Certificate?

The Export Certificate under Section 37 of the *Food and Drugs Act* is a certificate signed by the manufacturer and a Commissioner for Taking Oaths (Public Notary) to attest that the product for which the certificate is prepared is not manufactured or sold for Canadian consumption and its package and the contents do not contravene any known requirement of the law of the country for which it is or is about to be consigned. The International Trade Certificate is issued by the Natural Health Products Directorate of Health Canada, upon request and speaks to the regulatory and marketing status of the natural health product or site in Canada.

Q.6 What is the difference between an International Trade Certificate for Natural Health Products and a Certificate of Pharmaceutical Product (CPP)?

A CPP issued by the Inspectorate establishes the status of the pharmaceutical, biological, radiopharmaceutical or veterinary product authorized for sale under the *Food and Drug Regulations* and the GMP status of the fabricator of the product. The International Trade Certificate for natural health products is issued for natural health products authorized for sale under the *Natural Health Products Regulations* and for sites that possess valid site licences and are GMP compliant.

Q.7 How is the International Trade Certificate of Good Manufacturing Practices (GMP) Compliance different from the International Trade Certificate for Natural Health Products?

The International Trade Certificate of GMP Compliance is issued for a site located in Canada with a valid site licence issued under the *Natural Health Products Regulations*. It is not product specific, but speaks to the regulatory and compliance status of the specified site(s) authorized to conduct the following activities with respect to NHPs: manufacturing, packaging, labelling or importing. The International Trade Certificate for Natural Health Products is a product specific certificate which is issued for product that have received market authorization in Canada and that have been manufactured, packaged, labelled in licensed sites.

Q.8 If I invoke Section 37 of the *Food and Drugs Act* can I apply for an international trade certificate?

No. International Trade Certificates will not be not issued if Section 37 of the *Food and Drugs Ac*t is invoked.

Q.9 If I am importing natural health products into Canada for the purpose of export, can I apply for an International Trade Certificate for Natural Health Products?

No. The Natural Health Products Directorate does not issue certificates for products that are imported for the purposes of export only. NHPs that are imported into Canada for the purposes of sale in Canada must possess a valid product licence in the form of a Natural Product Number (NPN) or Drug Identification Number for Homeopathic Medicine (DIN-HM).

Q.10 How long will it take to receive my International Trade Certificate, after the request is submitted?

As this is done on a voluntary basis, NHPD does not commit to any specific time frame. However, we will make every effort to process these certificates in a timely manner.

Q.11 Are there fees that apply to the application for an International Trade Certificate?

No. The Natural Health Products Directorate does not currently charge for the issuance of ITCs. However, a fee system may be developed for these certificates in the near future.

Q.12 Am I required to show regulators in destination countries that the natural health product being exported is approved for sale in Canada?

It is up to the country of destination to make a decision with regards to a product's entry into their country. Exporters are encouraged to contact the consulate or regulatory authority for the country of destination for information on the requirements for import.

Q.13 Our company exports to two or three countries, can this be covered on one International Trade Certificate?

No. A certificate is country specific, naming one individual country as the country of destination.

Q.14 What is required to obtain an International Trade Certificate?

The following is required for each certificate:

1) International Trade Certificate: a valid product licence in the form of an NPN, or DIN-HM, and a site licence(s);
2) International Trade Certificate of GMP Compliance: a valid site licence.

Q.15 How do I apply for an International Trade Certificate?

An applicant may request an ITC by downloading and completing the templates found on the Health Canada website at: **www.healthcanada.gc.ca/nhp**. Applications must be submitted by mail to the following address:

Submission Management Division
Qualicum Tower A
2936 Baseline Rd.
AL 3302B
Ottawa, Ontario
K1A 0K9
(for courier K2H 1B3)

Applicants must include a completed shipping form (waybill Purolator, Fedex, Loomis, UPS, Dicom, etc.) and courier envelope with each request. Should a shipping form not be included with the request, the document will be returned to the applicant via regular mail.

Q.16 Whom do I contact for further information?

You can contact the Natural Health Products Directorate by email at: **NHPD_DPSN@hc-sc.gc.ca**.

APPENDIX A – INTERNATIONAL TRADE CERTIFICATE FOR NATURAL HEALTH PRODUCTS

INTERNATIONAL TRADE CERTIFICATE	Certificate No.: *Certificat n^{o} :*	***CERTIFICAT DE COMMERCE INTERNATIONAL***

exporter information / *renseignements sur l'exportateur*		
Exporting (certifying) country: *Pays exportateur (certificateur):*	**CANADA**	Importing (requesting) country: *Pays importateur (demandeur) :*
Name of applicant/exporter : *Nom du demandeur/exportateur :*		
Street address: *Adresse :*		
City: *Ville :*		Province: *Province :*
Country: *Pays :*		Postal code: *Code postal :*

Product Information / *Renseignements sur le produit*	
Product Licence Number / *Numéro de licence de mise en MarchÉ :*	Recommended Use or Purpose / *usage, fins recommandÉs:*

Product brand name / *marque nominative de produits :*	Dosage form / *Forme posologique :*

Route of administration: *Voie d'administration :*	Sterile dosage: *forme posologique stÉrile :*	☐ Yes *Oui*	☐ No *Non*

Medicinal ingredient(s) (common name): *Ingrédient(s) médicinal (médicinaux) (nom usuel) :*	Quantity/dosage unit: *Quantité par unité posologique :*	Potency (if any): *activitÉ (le cas échéant) :*

The above named product has been evaluated by Health Canada and is authorized for sale in Canada / *Santé Canada a évalué le produit susmentionné et a autorisÉ sa vente au Canada.*

SITE INFORMATION / *RENSEIGNEMENTS SUR LE SITE*

Authorized activities / *Activités autorisées*	**Building address / *Adresse du bâtiment***	**Site Licence No / *No. de licence d'exploitation***	**Date of expiry / *Date d'expiration***
Manufacturing / *Fabrication:*			
Packaging / *Emballage:*			
Labelling / *Étiquetage:*			

The above site(s) have been assessed for compliance with the Good Manufacturing Practice requirements of the Natural Health Products Regulations/ *Les sites et activités ci-dessus ont été évalués relativement à la conformité aux exigences des Bonnes pratiques de fabrication des Réglements sur les produits de santé naturels.*

certifying authority information / *renseignements sur autoritÉ de certification*

Address of certifying authority:	***Adresse d'autorité de certification:***
Natural Health Products Directorate 2936 Baseline Road, AL 3302B Ottawa, Ontario K1A 0K9	*Direction des Produits de santé naturels* *2936, chemin Baseline, IA 3302B* *Ottawa (Ontario) K1A 0K9*

Name of NHPD authorized official /
Nom du responsable autorisé de la DPSN:

Manager, Site Licence Assessment and Coordination Division / gestionnaire, *Division de coordination et d'évaluation des licences d'exploitation*	Date of issuance: *Date de délivrance :*

APPENDIX B – INTERNATIONAL TRADE CERTIFICATE OF GOOD MANUFACTURING PRACTICES COMPLIANCE

CERTIFICATE OF GMP COMPLIANCE	CERTIFICATE NO.: *CERTIFICAT N^O :*	*CERTIFICAT DE CONFORMITÉ AUX BPF*

This Certificate of Good Manufacturing Practice (GMP) Compliance is issued by Natural Health Products Directorate of Health Canada/ La Direction des produits de santé naturels de Santé Canada délivre le présent certificat.

SITE LICENCE HOLDER INFORMATION / *RENSEIGNEMENTS SUR LE TITULAIRE DE LICENCE D'EXPLOITATION*

Name of Applicant /
Nom du demandeur :

Street Address /
Adresse :

City /
Ville :

Province /
Province :

Country /
Pays :

Postal Code /
Code postal :

SITE INFORMATION / *RENSEIGNEMENTS SUR LE SITE*

Authorized Activities / *Activités autorisées*	Site Address / *Adresse du site*	Site Licence Number / *Numéro de licence d'exploitation*	Date of Expiry / *Date d'expiration*
Manufacturing / *Fabrication:*			
Packaging / *Emballage:*			
Labelling / *Etiquetage:*			
Importing / *Importation:*			

CERTIFYING AUTHORITY INFORMATION / *RENSEIGNEMENTS SUR AUTORITÉ DE CERTIFICATION*

ADDRESS OF CERTIFYING AUTHORITY	***ADRESSE D'AUTORITÉ DE CERTIFICATION***
Natural Health Products Directorate 2936 Baseline Road, AL 3300B Ottawa, Ontario K1A 0K9	*Direction des produits de santé naturels* *2936, chemin Baseline, IA 3300B* *Ottawa (Ontario) K1A 0K9*

Name of NHPD authorized official
Nom du responsable autorisé de la DPSN :

Manager, Site Licence Assessment and Coordination Division /
Gestionnaire, Division de coordination et d'évaluation des licences d'exploitation

Date of issuance /
Date de délivrance :

APPENDIX C - INSTRUCTIONS FOR COMPLETING TEMPLATES

Please do the following:

1) Print on both sides of the page.
2) Use legal size paper.
3) If the "certifying authority" box (last box) is spread over two pages, after the following text on the templates:

"The above site(s) have been assessed for compliance with the Good Manufacturing Practice requirements of the Natural Health Products Regulations/ Les sites et activités ci-dessus ont été évalués relativement à la conformité aux exigences des Bonnes pratiques de fabrication des Réglements sur les produits de santé naturels"

Click "enter" in the available box to add additional lines to move the "certifying authority" box completely to the next page. Further explanation provided in example 1 below:

4) Mail the completed ITC to NHPD.

The following information is to be completed by the applicant:

I. Country of Consignment:

a. **The Importing Country**: As only one country may be listed in this field, one form must be completed for each country of consignment and separate country-specific certificates will be issued.

II. Applicant Information:

a. **Applicant/Company Name**: The legal name of the applicant or company requesting the certificate. The certificate will bear this name.

Special note: If the applicant for the ITC is not also the Product Licence Number applicant or holder for the specified product, a letter from the Product Licence Number applicant or holder authorizing the applicant to export the specified product must be provided.

III. Product Information:

a. **NPN, DIN-HM Number**: The Natural Product Number (NPN) or Drug Identification Number – Homeopathic (DIN-HM) must be indicated, if applicable. Please note the abbreviation NPN or DIN-HM must precede the number.

b. **Dosage Form**: This must be the final physical form of the NHP which may be used by the consumer without requiring any further processing. (ex. Tablet, capsule etc.)

c. **Recommended Use**: Must be the therapeutic use or claim listed on the product label.

d. **Sterile Dosage Form**: Applicant must indicate either 'Yes' or 'No'.

e. **Medicinal Ingredients**: The Applicant is required to list all the medicinal ingredients by common name contained within the NHP.

f. **Quantity**: The quantity of the specified medicinal ~~and non-medicinal~~ ingredients per dosage unit must be listed.

g. **Potency**: The potency of the specified medicinal ~~and non-medicinal~~ ingredients per dosage unit must be listed if applicable.

IV. Site Information:

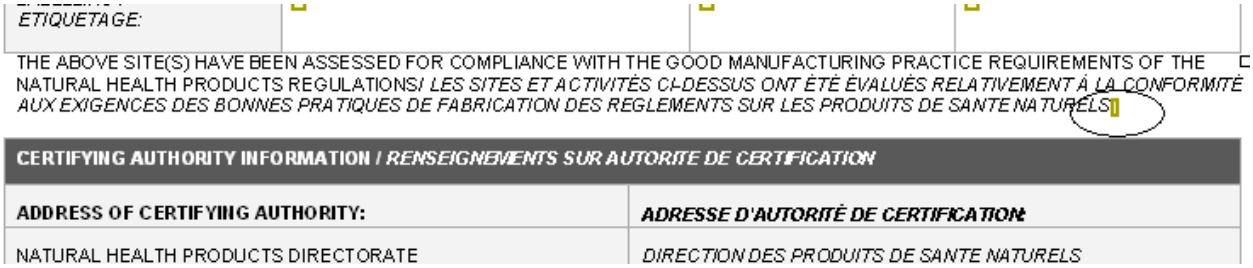
a. **Authorized Activities and Site Address**: The Applicant is required to provide the address of the manufacturer, packager, and labeller of the said product.

b. **Site Licence Number and Expiration Date:** Should the applicant have a valid SL number issued by Health Canada's NHPD, the applicant is required to list the SL number and expiry date in the indicated fields.

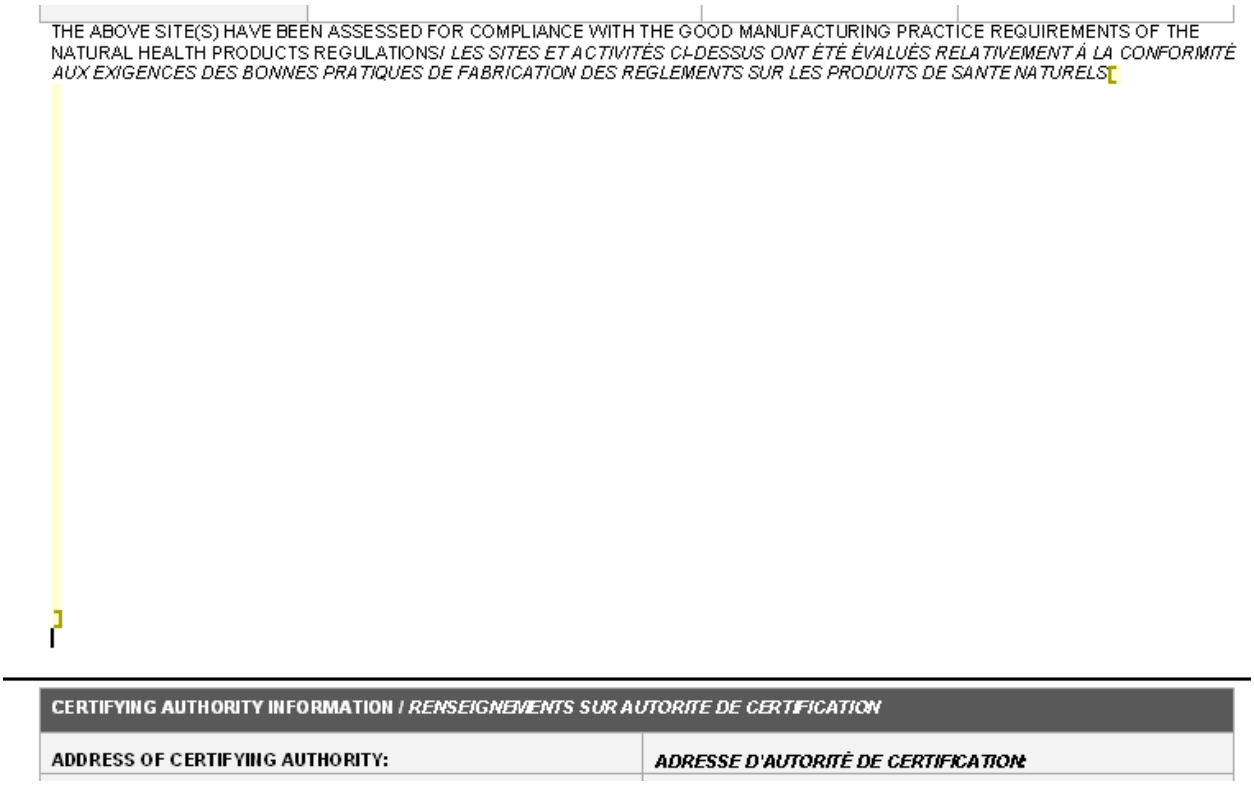
Example 1:

Verify the spatial arrangement of the template. For example, if the "Certifying Authority" box is on both sides of the page (split between the two sides of the page). The applicant will be required to make this adjustment. This can be done by pressing enter in the box after the site information until the "Certifying Authority" box has moved to the back side of the page.

Please see below:



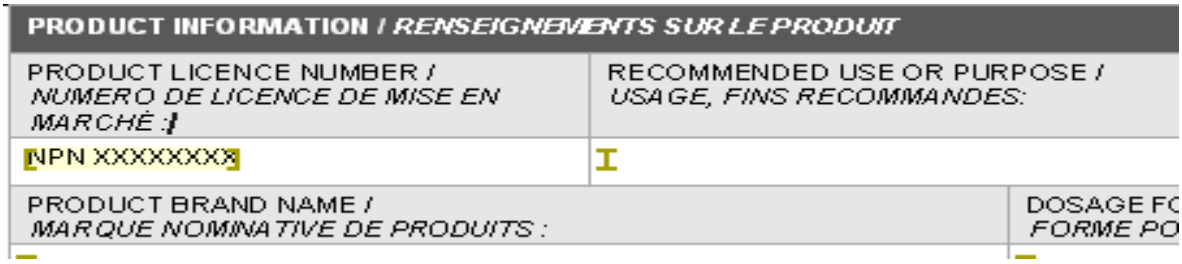
With the end result:



In order to be consistent with Section 91 of the Natural Health Products Regulations, please include the reference of DIN-HM and NPN before the 8 digit number on the ITC.

91. Every product number required by these Regulations to be shown on a label of a natural health product shall
(a) in the case of a homeopathic medicine, be preceded by the designation "DIN-HM"; and
(b) in any other case, be preceded by the designation "NPN".

Example:



APPENDIX D – REQUEST FOR STAMPING FORM

Request for Stamping

Submit this form with one copy of any material that is to be stamped.

The undersigned Company requests that Health Canada stamp and return a copy of the enclosed information for attachment to an International Trade Certificate (ITC).

Product Licence Number (if applicable):

Site Licence Number (if applicable):

Summary of attached information and material:

If an ITC has already been issued and stamping is now required, please provide the following information:

International Trade Certificate Number:

International Trade Certificate Security Label Number:

We certify that the attached information and material are accurate and up-to-date and that copies of this information and material are on file with Health Canada.

_____

Name of Company

_____ _____

Name of Company Representative **Title of Company Representative**

_____ _____

Signature of Company Representative **Date**

THIS DOCUMENT MUST BE SWORN BEFORE A NOTARY PUBLIC.

_____

Name

_____ (Seal)

Signature

_____

Date

This form may be subject to revision.