Health Canada Santé Canada

APPLICATION FOR INTERNATIONAL TRADE CERTIFICATE FOR NATURAL HEALTH PRODUCTS

NATURAL HEALTH PRODUCTS DIRECTORATE

November 2007
Version 2.0

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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1. INTRODUCTION

This document is intended to provide a general description of the Natural Health Products Directorate's international trade certificates for natural health products. Firms exporting natural health products from Canada are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the *Natural Health Products Regulations*. This international trade certificate is a document prepared by the Natural Health Products Directorate containing information about a product's regulatory or marketing status.

In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in Canada or meet specific Canadian regulations. Review of a Health Canada certificate may be a required part of the process to register or import a product into another country.

Under the Regulations, reference to the *Food and Drugs Act* and Regulations, the *Natural Health Products Regulations* or the Directorate on the label of or in any advertisement for a natural health product is strictly prohibited. An international trade certificate contains information about a product's regulatory and marketing status in Canada. The issuance of an international trade certificate does not suggest or imply that Health Canada sanctions any specific product. 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, if such action is warranted.

2. PRODUCTS FOR EXPORT ONLY

The *Natural Health Products Regulations* apply to the sale of natural health products and the manufacture, packaging, labelling, importation, distribution and storage of natural health products for the purpose of sale in Canada.

Section 101 of the *Natural Health Products Regulations* references Section A.01.045 of the *Food and Drug Regulations* and Appendix III to those Regulations, which apply in respect of natural health products. Products which are manufactured solely for the purpose of export do not fall under the scope of the *Food and Drugs Act* and the *Natural Health Products Regulations*.

Section A.01.045 of the *Food and Drug Regulations* references Section 37 of the *Food and Drugs Act*, which states that:

“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.”

The prescribed form is found in Appendix III of the *Food and Drug Regulations* and in Appendix A of this document. This certificate must be on record with the manufacturer for each product claiming exemption from the *Natural Health Products Regulations* on the basis of section 37 of the *Food and Drugs Act*. Health Canada asks that it be retained by the manufacturer for at least five years after the date of signature.

This certificate is signed by the manufacturer and a Commissioner for Taking Oaths to attest that the natural health product for which the certificate is prepared is not manufactured or sold for consumption in Canada 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.

3. INTERNATIONAL TRADE CERTIFICATE FOR NATURAL HEALTH PRODUCTS

3.1 Objectives

- To facilitate the customs process for the Canadian natural health products industry in destination countries, by voluntarily issuing certificates for natural health products regulated in Canada.
- To provide useful regulatory information to foreign regulatory authorities (information is included in certificates to assist authorities in properly determining the safety/quality status of a natural health product in the context of their own market and regulatory requirements).
- To be relevant in the international market place and acceptable to authorities in export destinations.

The certificate speaks to the regulatory and marketing status of the natural health product in Canada, but is not a guarantee of a product's safety or quality.

3.2 Policy Statement

A certificate of international trade for natural health products is not required under the *Natural Health Products Regulations*. The Natural Health Products Directorate voluntarily issues these certificates to facilitate the export process for Canadian manufacturers as a service to industry.

The Natural Health Products Directorate will issue three types of international trade certificates:

1. An **international trade certificate for natural health products** will be issued for those natural health products which possess a valid product licence in the form of a Natural Product Number (NPN), Homeopathic Medicines Number (DIN-HM), or a Drug Identification Number (DIN), and are manufactured, packaged and labelled in licensed sites. The relevant product and site information must be provided to the Natural Health Products Directorate at the time of application, as per the attached instructions.

2. An **international trade certificate for natural health products intended for export only** will be issued for those products which are manufactured for export only under Section 101 of the *Natural Health Products Regulations* and Section 37 of the *Food and Drugs Act*. The product must be labelled "export" or "export only." These products are not required to possess a valid product licence and are not required to be manufactured in licensed facilities.

   The applicant will attest to the Section 37 exemption for the product and must retain a copy of the completed Section 37 certificate in their files, to be provided

to the Natural Health Products Directorate upon request. This International Trade Certificate will be product specific, stating that the product is in compliance with Section 37 of the *Food and Drugs Act* and manufactured for export only.

If the product has been manufactured, packaged and / or labelled in facilities with a site licence, the certificate will indicate the sites are compliant with the Good Manufacturing Practices outlined in Part 3 of the *Natural Health Products Regulations*. If the product has been manufactured, packaged and labelled in sites without a site licence, the certificate will indicate that the sites have not been assessed for compliance with the Good Manufacturing Practices outlined in the *Natural Health Products Regulations*.

To obtain this certificate, the product must be manufactured at a site in Canada. The Natural Health Products Directorate does not issue certificates for products that are imported for the purposes of export only.

3. A **certificate of good manufacturing practices (GMP) compliance** will be issued for sites which are assessed by the Natural Health Products Directorate to meet the GMP requirements outlined in Part 3 of the *Natural Health Products Regulations*. The sites must have a valid site licence and the certificate will clearly indicate the date of issuance, the authorized activities and the required date of renewal of the site licence. This certificate is not product specific. All or any of the sites on the site licence that are located in Canada may be listed on the certificate.

The International Trade Certificates are country specific, naming one individual country as the country of destination. The GMP Certificate of Compliance does not name the country of destination.

3.3 Applicants

The International Trade Certificate applicant must be located in Canada. In the case of natural health products that have a product licence, if the applicant is not also the product licence holder, a letter from the product licence holder authorizing the applicant to export the product must accompany the application. In the case of natural health products without a product licence, if the International Trade Certificate applicant does not have legal ownership or responsibility for that product, a letter from the company or individual with legal responsibility for that product must accompany the application.

When requested to issue an International Trade Certificate, the Natural Health Products Directorate will also consider any current compliance and enforcement action being taken against the product, site or applicant in question.

3.4 Stamping of documents to accompany an International Trade Certificate

If documents related to the product or site indicated on the certificate need to be stamped by the Natural Health Products Directorate, the applicant must:

- fill out the "Request for Stamping Form", which is included in this document as Appendix E;
- have the form sworn before a Commissioner for taking oaths (Notary Public); and
- submit the form with TWO copies of the information to be stamped. One copy is stamped and returned to the applicant and the other copy is retained in the Natural Health Products Directorate's files.

The "Request for Stamping Form" should accompany an ITC application. Certificate holders, who were unaware at the time of applying for an ITC of an importing authority's stamping requirements, 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 holder of the product licence (PL 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 also 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 SOP, stability record, etc.); and
- 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.).

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.

3.5 Fees

The Natural Health Products Directorate does not currently charge for the issuance of these certificates. As this is a voluntary service provided by the Natural Health Products Directorate, it is anticipated that a fee system will be developed for these certificates, in the near future.

Applicants must include a completed shipping form (waybill Purolator, Fedex, Loomis, UPS, Dicom, etc.) with each request.

3.6 Cover Letter

The Natural Health Products Directorate's international trade certificate for natural health products intended for export only will be accompanied by a cover letter that includes information on the regulatory regime governing natural health products in Canada. If the applicant does not intend to sell products in Canada, no site or product licence is required pursuant to the exemption in Section 37 of the *Food and Drugs Act* (see section 2 above).

This cover letter will be posted on the Natural Health Products Directorate's website. It is not necessary to request this letter from the Natural Health Products Directorate. It will be automatically included with the international trade certificate for natural health products intended for export only.

4. DEFINITIONS

Certificate of GMP Compliance: A certificate issued by a Regulatory Authority attesting to compliance with good manufacturing practices of a manufacturing, packaging or labelling site in that country.

Certificate of Pharmaceutical Product (CPP): A certificate issued by the Health Products and Food Branch Inspectorate establishing the status of the pharmaceutical, biological or radiopharmaceutical product and the GMP status of the applicant. This certificate is in the format recommended by the World Health Organization (WHO).

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**

Commissioner for Taking Oaths: Person authorized to swear affidavits.

Drug Identification Number (DIN): The Drug Identification Number (DIN) is the number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic Products Directorate (TPD) and approved for sale in Canada.

Export Certificate (under Section 37 of the *Food and Drugs Act*): A certificate signed by the manufacturer and a Commissioner for Taking Oaths to attest that the NHP for which the certificate is prepared is not manufactured or sold for consumption in Canada and that its package and the contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned.

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 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.

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) / Homeopathic Medicine Number (DIN-HM): An eight (8) digit numerical code assigned to each natural health product approved to be marketed under the *Natural Health Products Regulations.* **Homeopathic Medicine Number (DIN-HM):** An eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the *Natural Health Products Regulations.*

NHP International Trade Certificate: A certificate which speaks to the regulatory and marketing status of the natural health product in Canada but is not a guarantee of a product's safety or quality**.**

Proper name: In respect of an ingredient of a natural health product, one of the following:

a) if the ingredient is a vitamin, the name for that vitamin set out in item 3 of Schedule 1;
b) if the ingredient is a plant or a plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet; and
c) if the ingredient is other than one described in paragraphs (a) or (b), the chemical name of the ingredient.

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.

5. FREQUENTLY ASKED QUESTIONS CONCERNING INTERNATIONAL TRADE CERTIFICATES UNDER THE *NATURAL HEALTH PRODUCTS REGULATIONS*

Q's and A's

Q.1 What is a Natural Health Product International Trade Certificate?
A certificate which speaks to the regulatory and marketing status of the natural health product in question, but is not a guarantee of the product's safety or quality.

Q.2 Do I require a 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 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 Health Canada's approval of a product?
No. An international trade certificate contains information on the regulatory and marketing status of the product in Canada. The issuance of a certificate does not suggest or imply that Health Canada approves or sanctions any specific product. It is the responsibility of the product licence holder to market a safe and properly labelled product.

In order to market a natural health product in Canada, the product must be compliant with the *Natural Health Products Regulations*. All natural health products in Canada require pre-market authorization in the form of a valid NPN, DIN-HM, or a DIN, and must be manufactured, packaged and labelled in licensed facilities.

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.

Q.5 What is the difference between an Export Certificate completed under Section 37 of the Food and Drug Act and an NHP 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 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 NHP International Trade Certificate is issued by the Natural Health Products Directorate of Health Canada, upon submission of an application package, including information on the regulatory status of the product in Canada. An international trade certificate speaks to the regulatory and marketing status of the natural health product in Canada.

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

A CPP is a certificate based on the WHO format, which is issued by the Health Products and Food Branch Inspectorate for pharmaceutical, biological or radiopharmaceutical products.

The NHP International Trade Certificate is issued for those products classified as natural health products under the *Natural Health Products Regulations*.

Q.7 How is the Certificate of GMP Compliance different from the NHP International Trade Certificate?

The 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 natural health products: manufacturing, packaging, labelling or importing.

The NHP International Trade Certificate is a product specific certificate which speaks to the regulatory and marketing status in Canada of the specified product.

Q.8 Should I discontinue using the Canadian Food Inspections Agency's Manufacturer's Declaration and apply for the NHP International Trade Certificate?

This depends on the product(s) you are exporting. CFIA will continue to issue the Manufacturer's Declaration document to those products which meet the food definition in the *Food and Drugs Act.* Those products which meet the definition of an NHP according to the *Natural Health Products Regulations* will need to apply for the NHP International Trade Certificate.

To sell a natural health product in Canada, NHPs must be fully compliant with the *Natural Health Products Regulations* and possess pre-market authorization in the form of a valid NPN, DIN-HM, or a DIN.

Q.9 If I invoke Section 37 of the *Food and Drugs Act,* do I also need to apply for a NHP International Trade Certificate for NHPs for Export Only?

This is the manufacturer's choice. An export certificate in the format described under Section 37 of the *Food and Drugs Act* will satisfy Health Canada that the specified product(s) does not fall under the purview of the *Natural Health Products Regulations*. The NHP International Trade Certificate may facilitate the entry of natural health products in other countries, by providing information to foreign regulatory authorities on the regulatory and marketing status of the product in Canada.

Q.10 If I am importing Natural Health Products into Canada for the purpose of export, can I apply for an NHP International Trade Certificate?

No. The Natural Health Products Directorate does not issue certificates for products that are imported for the purposes of export only. Natural Health Products that are imported into Canada for the purposes of sale in Canada must be fully compliant with the *Natural Health Products Regulations* and possess pre-market authorization in the form of a valid NPN, DIN-HM, or a DIN.

Q.11 How long will it take to receive my NHP International Trade Certificate, after the application 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 applications in a timely manner. You will receive your certificate as soon as your application has been reviewed.

Q.12 Are there fees that apply to the application for an NHP International Trade Certificate?

No. The Natural Health Products Directorate does not currently charge for the issuance of these certificates. However, it is anticipated that a fee system will be developed for these certificates in the near future.

Applicants must include a completed shipping form (waybill Purolator, Fedex, Loomis, UPS, Dicom, etc.) with each request.

Q.13 Am I required to show regulators in destination countries that the natural health product is approved for sale in Canada?

It is up to the country of destination to develop and enforce any requirements for 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.14 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.15 What is required to obtain an NHP International Trade Certificate? Is there only one type of International Trade Certificate application?

There are three different types of applications. The following is required for each:

1) NHP ITC for NHPs with marketing authorization: a valid product licence in the form of an NPN, DIN-HM, or DIN and a site licence(s);
2) NHP ITC for NHPs for Export Only: Products must be manufactured, packaged and labelled for export only and the manufacturer and the ITC applicant must retain a copy of the completed Section 37 Export Certificate in their files for each product; and
3) Certificate of GMP Compliance: a valid site licence.

Q.16 Our company is selling natural health products with DINs. Can I apply for an NHPD International Trade Certificate?

1) Yes. The two conditions for issuing an International Trade Certificate for DIN'd NHPs are as follows:

- the NHP company must currently hold a valid site licence and;
- the product for which the ITC is requested must have a valid NPN, DIN-HM or DIN.

Q.17 How do I apply for an NHP International Trade Certificate?

You can download the application form and instructions from the NHPD website at: **www.healthcanada.gc.ca/nhp** or you can order a paper copy by calling 1-888-774-5555. 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.) with each request.

Q.18 Whom do I contact for further information?

You can contact the Natural Health Products Directorate by email at: **NHPD_DPSN@hc-sc.gc.ca** or by calling 1-888-774-5555.

APPENDIX A – SECTION 37 EXPORT CERTIFICATE (FOR EXPORT ONLY PRODUCTS)

(Under the *Food and Drugs Act**--R.S.C. 1970, c. F-27)

The undersigned exporter hereby certifies that the (description of article)

_____

packaged and labelled as
follows:_____

and marked in distinct overprinting with the word "Export"

1. is not manufactured for consumption in Canada,

2. is not sold for consumption in Canada, and

3. packages and the contents of such packages do not contravene any known requirement of the law of
_____ to
which it is or is about to be (name of country or countries) consigned.

Dated at_____the_____day
of_____20____
Canada : In the matter of an Export Certificate under the *Food and Drugs Act*, Province of\

_____

To Wit : I,

_____

of
the_____of_____

in
the_____of_____

do solemnly declare:

1. that I am the "Exporter" issuing the certificate above set out and have a knowledge of the matters and facts herein declared to by me,

or

I am
the_____of_____

_____

the "Exporter" issuing the certificate above set out and have a knowledge of the matters and facts herein declared to by me (describe position of declarant as the agent of the "Exporter" in case of a Corporation issuing the certificate),

2. that the information set out in the said certificate is true.

3. that all information relevant to the purpose of the said certificate is set out herein and no information relevant thereto has knowingly been withheld.

And I make this solemn declaration conscientiously believing it to be true, and knowing that it is of the same force and effect as if made under oath, and by virtue of *The Canada Evidence Act*.

Declared before me
at_____this_____

day of_____20_____.

_____ _____
A Commissioner for Taking Oaths

* See section 37 of the *Food and Drugs Act*, Section 101 of the *Natural Health Products Regulations* and Appendix III of the *Food and Drug Regulations*

APPENDIX B – APPLICATION FORM FOR INTERNATIONAL TRADE CERTIFICATE

This form is for applicants who hold Product and Site Licences.

I. HC USE ONLY		
File Number:	Submission Number:	Date/Time of Receipt:

Instructions on how to complete this application form are available further below.

II. Country of Consignment			
Name of country:			
III. Applicant/Company			
Applicant/Company name:		Company Code (if known):	
Street/Suite/Land Location:			
City:	Province:	Country:	Postal Code:
IV. Contact Information			
Surname:	Given Name:	Title:	
Street/Suite/Land Location:			
City:	Province:	Country:	Postal Code:
Telephone No:	Fax No:	E-mail:	
V. Product Information			
Product Licence No:		Brand Name:	
Recommended Use(s) of Purpose(s):		Dosage Form:	
Route of Administration:		Sterile Dosage: □ Yes □ No	

Medicinal Ingredients: (By common name)	Quantity/dosage unit:	Potency (if any):

Non Medicinal Ingredients:

VI. Site Information

Authorized Activities:	Site Address:	Site Licence Number:	Date of Expiry:

VII. Attestation

☐ I certify that the above mentioned product is manufactured, packaged and labelled in compliance with the Good Manufacturing Practice requirements of the *Natural Health Products Regulations*.

☐ If the above- mentioned product is produced at a foreign site; I certify that I have evidence it complies with the Good Manufacturing Practices (GMP) requirements of the *Natural Health Products Regulations*.

I, the undersigned, certify that the information in this International Trade Certificate application is accurate and complete.

_____ _____

Signature of Applicant Date

Number of certificates requested:
The certificate may be returned by: ☐ Prepaid Courier (a completed shipping form is included with this application e.g waybill Purolator, UPS, Fedex etc.) ☐ Regular Mail
Certificates: ☐ English ☐ French

Instructions for Completing the Form

I. To be completed by Health Canada.

The following information to be provided by the applicant:

II. **Country of Consignment:** The importing country (e.g. Japan, Nigeria). One form must be completed for each country of consignment and separate, country-specific certificates will be issued.

III. **Applicant Information:**

Applicant/Company name: The legal name of the applicant or company. The certificate will be issued to and will bear this name.

If the applicant for the International Trade Certificate is not also the product licence holder for the specified product, a letter from the product licence holder authorizing the applicant to export the specified product must be provided or the PL holder's signature.

Address of Applicant/Company: The full address of the applicant in Canada. The certificate will be mailed to this address.

IV. **Contact Information:** Telephone and Facsimile number of applicant, including area code, e-mail address

V. **Product Information:**

The product information provided in the application must be identical to the product information contained in the product licence.

Product Licence Number: A number, preceded by the prefix NPN or, in the case of a homeopathic medicine, DIN-HM 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 sell the specified natural health product in Canada.

Dosage Form: The final physical form of the natural health products which may be used by the consumer without requiring any further processing. For example: tablets, gel.

Recommended Use: The therapeutic use or claim listed on the label. For example: for minor throat irritations.

Sterile dosage form: A dosage form that is free from microbial contamination.

Medicinal Ingredients: Listing by common name of the medicinal ingredients contained within the natural health product.

Non-Medicinal Ingredients: Listing by common name of the non-medicinal ingredients contained within the natural health product.

Quantity: List the quantity of the specified medicinal ingredient and if applicable, for non medicinal ingredients per dosage unit. For example: for a 500mg tablet of Vitamin C, Quantity: 500 mg.

Potency: This is the component to which the amount (amount per dosage unit which further characterizes the quantity of the ingredient) applies. For example: 5% hyperforin.

VI. Site Information:

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.

Expiry Date: The date on which the site licence expires, if not renewed in accordance with the provisions set out in the *Natural Health Products Regulations* and Site Licensing Guidance Document.

APPENDIX C – APPLICATION FORM FOR INTERNATIONAL TRADE CERTIFICATE – FOR EXPORT ONLY

I. HC USE ONLY		
File Number:	Submission Number:	Date/Time of Receipt:

Instructions on how to complete this application form are available further below.

II. Country of Consignment			
Name of country:			
III. Applicant/Company			
Applicant/Company name:		Company Code (if known):	
Street/Suite/Land Location:			
City:	Province:	Country:	Postal Code:
IV. Contact Information			
Surname:	Given Name:	Title:	
Street/Suite/Land Location:			
City:	Province:	Country:	Postal Code:
Telephone No:	Fax No:	E-mail:	
V. Product Information			
Brand Name:			
Recommended Use(s) of Purpose(s):		Dosage Form:	
Route of Administration:		Sterile Dosage: □ Yes □ No	

Medicinal Ingredients: (By common name)	Quantity/dosage unit:	Potency (if any):

Non Medicinal Ingredients:

VI. Site Information

Authorized Activities:	Site Address:	Site Licence Number:	Date of Expiry:

VII. Attestation

☐ I attest that this product has been manufactured solely for export, in compliance with Section 37 of the Food and Drugs Act. It is not authorized for sale in Canada.

I, the undersigned, certify that the information in this International Trade Certificate application is accurate and complete.

_____ _____

Signature of Applicant Date

Number of certificates requested:
The certificate may be returned by: ☐ Prepaid Courier (a completed shipping form is included with this application e.g waybill Purolator, UPS, Fedex etc.) ☐ Regular Mail
Certificates: ☐ English ☐ French

Instructions for Completing the Form

I. To be completed by Health Canada.

The following information to be provided by the applicant:

II. Country of Consignment: The importing country (e.g. Japan, Nigeria). One form must be completed for each country of consignment and separate, country-specific certificates will be issued.

III. Applicant Information:

Applicant/Company name: The legal name of the applicant or company. The certificate will be issued to and will bear this name.
If the applicant for the International Trade Certificate is not also the product licence holder for the specified product, a letter from the product licence holder authorizing the applicant to export the specified product must be provided or the PL holder's signature.

Address of Applicant/Company: The full address of the applicant in Canada. The certificate will be mailed to this address.

IV. Contact Information: Telephone and Facsimile number of applicant, including area code, e-mail address

V. Product Information:

Dosage Form: The final physical form of the natural health products which may be used by the consumer without requiring any further processing. For example: tablets, gel.

Recommended Use: The therapeutic use or claim listed on the label. For example: for minor throat irritations.

Sterile dosage form: A dosage form that is free from microbial contamination.

Medicinal Ingredients: Listing by common name of the medicinal ingredients contained within the natural health product.

Non-Medicinal Ingredients: Listing by common name of the non-medicinal ingredients contained within the natural health product.

Quantity: List the quantity of the specified medicinal ingredient and if applicable, for non medicinal ingredients per dosage unit. For example: for a 500mg tablet of Vitamin C, Quantity: 500 mg.

Potency: This is the component to which the amount (amount per dosage unit which further characterizes the quantity of the ingredient) applies. For example: 5% hyperforin.

VI. Site Information:

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.

Expiry Date: The date on which the site licence expires, if not renewed in accordance with the provisions set out in the *Natural Health Products Regulations* and Site Licensing Guidance Document.

APPENDIX D – APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE CERTIFICATE OF COMPLIANCE

I. HC USE ONLY		
File Number:	Submission Number:	Date/Time of Receipt:

Instructions on how to complete this application form are available further below.

II. Country of Consignment			
Name of country:			
III. Applicant/Company			
Applicant/Company name:		Company Code (if known):	
Street/Suite/Land Location:			
City:	Province:	Country:	Postal Code:
IV. Contact Information			
Surname:	Given Name:	Title:	
Street/Suite/Land Location:			
City:	Province:	Country:	Postal Code:
Telephone No:	Fax No:	E-mail	

V. Site Information			
Authorized Activities:	Site Address:	Site Licence Number:	Date of Expiry:

VI. Attestation
☐ I attest that sites and operations are in compliance with the Good Manufacturing Practice requirements of the *Natural Health Products Regulations*. I, the undersigned, certify that the information in this International Trade Certificate application is accurate and complete. _____ _____ Signature of Applicant Date

Number of certificates requested:
The certificate may be returned by: ☐ Prepaid Courier (a completed shipping form is included with this application e.g waybill Purolator, UPS, Fedex etc.) ☐ Regular Mail
Certificates: ☐ English ☐ French

Instructions for Completing the Form

I. To be completed by Health Canada.

The following information to be provided by the applicant:

II. Country of Consignment: The importing country (e.g. Japan, Nigeria). One form must be completed for each country of consignment and separate, country-specific certificates will be issued.

III. Applicant Information:

Applicant/Company name: The legal name of the applicant or company. The certificate will be issued to and will bear this name.

Address of Applicant/Company: The full address of the applicant in Canada. The certificate will be mailed to this address.

IV. Contact Information: Telephone and Facsimile number of applicant, including area code, e-mail address

V. Site Information:

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.

Expiry Date: The date on which the site licence expires, if not renewed in accordance with the provisions set out in the *Natural Health Products Regulations* and Site Licensing Guidance Document.

APPENDIX E – REQUEST FOR STAMPING FORM

Request for Stamping

Submit this form with two copies of any material that is to be stamped. One copy of the material will be stamped and returned to you with your Certificates. The other copy will be retained in Health Canada's files.)

The undersigned Company requests that Health Canada stamp and return one 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.