Health Canada Santé Canada

Protected B when completed

Trading Partner Agreement – NHP Online

Between:

Legal (Registered) name: _____

domiciled in (Province or State): _____

Country: _____

(Hereinafter referred to as "the Trading Partner")

-And-

His Majesty the King in Right of Canada ("the Crown") as represented by the Minister of Health for Canada, through Natural and Non-prescription Health Products Directorate (the "NNHPD")

(collectively referred to herein as the "Parties")

Whereas:

(a) Natural Health Product licensing and assessments are regulated under the *Natural Health Products Regulations* (SOR/2003-196) (the "Regulations");

(b) the NNHPD, a Directorate of the Health Canada Department, administers licensing and assessments of natural health products;

(c) the Parties have entered or propose to enter into one or more Transaction(s) for the application requirements for one or more licences for sites or products to be assessed under the Regulations;

(d) the Trading Partner wishes to submit its licence application electronically; and

(e) the Parties want to set out the terms and conditions under which the Trading Partner will submit information, in an electronic format determined by the NNHPD, to support a request of licence for a natural health product or site.

Canada

Now Therefore,

the Parties agree as follows:

1.0 Definitions

1.1 The definitions set out in section 1 of the Regulations apply to words and expressions in this Agreement that are identical to those words and expressions defined in section 1 of the Regulations.

1.2 In this Agreement, the following words and expressions shall have the meanings set out below:

a) **"Applicant"** is the Primary User or the Delegated User as assigned by the Primary User to provide the information and supporting documentation required by the NNHPD to assess the application and issue a licence if approved by the NNHPD

b) **"Canada Post epost Connect Network(s), Mailbox (es)"** means the configuration of computer processing and communications facilities of Canada Post Corporation by means of which the Documents are transmitted and received by the Parties through epost Connect functionality and secure environments;

c) **"Confidential Information"** means with respect to each of the Parties to this Agreement respectively, the information and trade secrets of that party and the information and trade secrets of other persons in favour of which that party has undertaken, or is otherwise bound by, an obligation of confidentiality, regardless of the form in which such information is constituted, excluding however, information that is demonstrated by the party seeking entitlement to an exemption to comprise: information which has become publicly available other than as a result of the conduct of that party, information within the party's knowledge prior to the effective date of this Agreement; and information that has been lawfully and legitimately disclosed to that party by another source;

d) **"Delegated User"** is a person who is designated by the Primary User as having the authority on behalf of the Trading Partner to use the NHP Online system;

e) **"Document"** means any licence application, status notice, application for assessment and/or any other additional documentation prescribed by any regulation made under the *Natural Health Products Regulations* (SOR/2003-196) which are to be transmitted electronically between the Parties and Health Canada;

f) **"Enrolled User"** is a Primary User or a Delegated User who has been confirmed by the NNHPD as accepted for use of the NHP Online system;

g) **"Health Canada's Departmental Network(s)"** means the configuration of computer processing and communications facilities of Health Canada by means of which the Documents are transmitted and received by the Parties;

h) **"Health Canada's Electronic Exchange Protocol(s)"** means the protocol(s) specified by Health Canada as that governing the requirements of format structure and transmission of the Documents and other communications between the Parties and NHP Online.

i) **"Ingredients Database"** is a collection of natural health product ingredients set out in a database maintained by the NNHPD;

j) **"NHP Online system"** is a Protected B-level Web-based suite of integrated business components to handle natural health product licence applications and site licence applications from the Trading Partner (Applicant).

k) **"Primary User"** is an officer of the Trading Partner, who is duly authorized to sign this Agreement on behalf of the Trading Partner, and who may designate a Delegated User for purposes of using the NHP Online system.

l) **"Program Enrolment"** is the process by which the Applicant is authorized by the NNHPD to use an Authentication Identifier to receive services or enter into Transactions with the NNHPD for any program as authorized by the NNHPD.

m) **"epost Connect"** is the proprietary communication product provided and supported by Canada Post Corporation which will be used by the Trading Partner to submit information related to a natural health product licence application.

n) **"Receipt Computer"** means, with reference to each party, the computer designated from time to time, by THE NNHPD, where all documentation, information and correspondence will be sent with respect to application for licences;

o) **"Receiver"** in relation to a Document means the party that receives it;

p) **"Sender"** in relation to a Document means the party that transmits it;

q) **"Transaction"** means the sending by the Sender and the receipt by the receiver of the Document defined by this Agreement via epost Connect and Health Canada's Departmental Network; and

r) **"Transaction log"** means the record of all the Documents and other communications exchanged between the Parties via epost Connect and Health Canada's Departmental Network.

2.0 Compliance with Health Products Licensing

2.1 Prerequisites

2.1.1 In order to participate in the electronic exchange of licensing application information, an account must be set up with epost Connect communication service which is an integral part of this Agreement.

2.1.2 The Parties agree that all information exchanges between them in respect of documents as defined in this Agreement shall be governed by this Agreement, regardless of the form of document used to exchange information, be it electronic or paper, as permitted by law.

2.1.3 As set out in this Agreement, the Trading Partner will identify, authenticate and authorize persons to act on its behalf to submit information or to perform any other transactions as authorized by the NNHPD; and

2.1.4 The Trading Partner will, in accordance with this Agreement, be responsible for the subscription and access to the epost Connect services through a separate agreement with Canada Post Corporation.

2.2 No exemption

2.2.1 The Parties acknowledge that participation in the electronic exchange of information under this Agreement does not exempt the Trading Partner from its obligation under all applicable legislation, including but not limited to federal, provincial and municipal statutes, regulations and by-laws, which may be in force from time to time.

3.0 Operation of Health Canada Departmental Network and epost Connect Services

3.1 Creation and Readiness Notification

The Trading Partner shall obtain, install, test and maintain, at its own expense, the necessary infrastructure, including but not limited to the computer equipment, supporting equipment, software and services, including communications infrastructure services that it will require in order to send and to receive documents using the epost Connect communication service to NHP Online. These requirements will be posted on the Health Canada NHP Online website.

3.2 Documents Standards

Each Document transmitted by a party via Canada Post epost Connect communication service shall be structured and transmitted in accordance with the Health Canada's Electronic Exchange Protocol(s). When the standard adopted for Documents is officially changed or modified by the issue of a new version or release of the software, the Parties shall co-operate to effect the change in a commercially reasonable manner.

3.3 Network Review

Health Canada shall periodically review the appropriateness and operation of epost Connect communication service and Health Canada Departmental Network and shall co-operate in implementing such changes or modifications as may be needed. The NNHPD reserves the right to make all final decisions regarding NHP Online within the Health Canada Departmental Network(s).

4.0 Use of NNHPD Application of the Health Canada Departmental Network

4.1 Transaction Documents

Each Document shall conform to and contain all of the required information specified to support the licence application and its assessment.

4.2 Proper Receipt

A Document will be deemed to have been received when it is accessible to the Receiver at its Receipt Computer. Receipt of a Document is not **prima facie** evidence of the accuracy and completeness of its contents.

5.0 Reliability of Health Canada Departmental Network – epost Connect and /or NNHPD Components

5.1 Authorisation

Each party shall establish such system or method of controlling the transmission of its Documents as it considers appropriate, and warrants that each Document of which it is the Sender is duly authorised by it and binds it.

5.2 Security

5.2.1 Each party shall undertake all commercially reasonable steps necessary to prevent unauthorised access to and use of any portion of epost Connect and/or Health Canada's Departmental Network that is under its control.

5.2.2 The Trading Partner, through its Primary User, undertakes to notify the NNHPD of any suspected inappropriate use of the Health Canada Departmental Network including possible fraudulent use, misrepresentation, loss, damage or theft of epost Connect account information and / or other security devices including corruption of same.

5.3 Incomplete, Inaccurate or Corrupted Documents

5.3.1 The followings actions shall be at the expense of the initiating party:

(a) If the Receiver of a Document(s) or other communication via epost Connect or Health Canada's Departmental Network reasonably suspects that it is incomplete, inaccurate, corrupted in transmission, or not intended for the Receiver, the Receiver shall promptly notify the Sender and request clarification. The Receiver shall not otherwise act in reliance upon any such Document(s) via the Health Canada's Departmental Network, pending clarification by the Sender;

(b) The Applicant shall provide complete and accurate information as indicated in the guidelines published on the Health Canada, NNHPD website.

(c) The Applicant shall ensure the authenticity of the information provided in the electronic version of the Document(s);

(d) If the Applicant suspects any information via epost Connect and Health Canada's Departmental Network did not originate from their organization he/she shall immediately notify the NNHPD; and

(e) The Applicant shall immediately notify the NNHPD if the Applicant suspects the integrity of its epost Connect account may have been compromised.

5.4 Confidentiality

5.4.1 Each party acknowledges that the Documents may contain Confidential Information of the other party. Each party shall notify any personnel who may have access to the Documents of a confidential nature of such information and shall instruct such personnel to read, understand and adhere to each party's procedures and guidelines for handling sensitive or confidential data, such as, to refrain from disclosing such information unless such disclosure is required by law and except to the extent reasonably necessary to enable the performance of their duties and to undertake all reasonable steps necessary to preserve the confidentiality and integrity of Confidential Information of the other party including the exercise of not less than the same degree of discretion and precaution applicable with respect to the Confidential Information of the party by which they are engaged.

5.4.2 The NNHPD will make all reasonable efforts to ensure the privacy of the Documents sent pursuant to a Transaction under this Agreement, but cannot absolutely guarantee such privacy given the current regulatory and technological environment.

5.5 Availability of epost Connect, NNHPD Network

5.5.1 The NNHPD makes no warranty as to the availability of the NHP Online system, and accepts no responsibility for its unavailability due to any cause beyond its control or that the NNHPD could not have reasonably prevented by means of controls, compromise, disaster recovery procedures, business continuity procedures, and that occurred without the fault of the NNHPD.

5.5.2 The epost Connect functionality falls under the subscription and Service Level Agreement between the Trading Partner and Canada Post, and the NNHPD makes no representation of availability for epost Connect.

5.6 Protection of Trading Partner's Computer Networks

5.6.1 The Trading Partner warrants that it will use the relevant NHP Online Documents on computer equipment that is regularly scanned for viruses and use of malicious programs, and accepts responsibility for any and all use of its computer networks in regard to the NNHPD.

5.6.2 The Trading Partner is advised that it should establish and implement reasonable security measures, including the following:

(i) Implementing desktop anti-virus and malware protection and keeping these products up to date

(ii) Keeping client workstations current by applying security and functionality patches and updates on a regular basis

(iii) Protecting client workstations using firewall services;

(iv) Implementing configuration and change management processes and procedures for the client environment to maintain an acceptable security posture;

(v) Maintaining a clear separation of duty between system administration, oversight activities and system users;

(vi) Implementing appropriate role based access controls for the safeguarding of protected and confidential information contained in the Documents

5.7 Program Enrolment

5.7.1 Upon written notification by the Primary User, on behalf of the Trading Partner, to the NNHPD that the identity of an individual has been authenticated and the individual is thereby authorized by the Trading Partner to act on its behalf for purposes of the NHP Online system, the NNHPD will ordinarily enrol the individual in the NHP Online system, but reserves the right to refuse such enrolment.

5.7.2 The Trading Partner agrees that when the Enrolled User uses epost Connect to submit information, the Enrolled User is deemed to have signed and issued the documents containing the information and is deemed to have done so on behalf of, and as authorized by, the Trading Partner.

5.7.3 The Trading Partner certifies that, in any request for authentication or program enrolment, information provided to the Applicant for purposes of NHP Online enrolment is accurate and complete. The Trading Partner further certifies to the NNHPD that, in seeking enrolment to the NHP Online system for its Primary User and Delegated User(s), it has no information or knowledge that the identity of the Primary User or Delegated User is inaccurate, incomplete or has been changed or altered, and that they are authorized to be enrolled accordingly.

5.8 Disaster Recovery

If Health Canada's Departmental Network ceases to be available to the Parties by reason of some failure of equipment or services (whether or not caused by a party or constituting force majeure as described in section 6.3), each party will use its best efforts (a) to continue normal communications between it and the other party by alternate means, (b) to take such reasonable steps to ensure that Health Canada's Departmental Network is restored to normal operating condition as soon as reasonably practicable, and (c) to revert to paper-based licence application should Health Canada's Departmental Network be unavailable for an extended period of time.

5.9 Notification of the NNHPD

The Trading Partner agrees to notify the NNHPD if it has reason to believe that there has been a breach in the terms and conditions of this Agreement, or any act or omission of the Trading Partner's Enrolled User(s) that would be in breach of this Agreement and shall take all necessary steps to remedy such breach, including but not limited to, the measures set out in section 5.10 below.

5.10 Suspension or Revocation of Program Enrolment to the NHP Online system

5.10.1 The Trading Partner must, by notice in accordance with section 7.3, request revocation or suspension of an Enrolled User, or remove access of an Enrolled User, to the NHP Online system, if:

(a) that person no longer has the authority to perform the duties on behalf of the Trading Partner;

(b) the username or password of that person is compromised or insecure, or suspected of being compromised or insecure; or

(c) that person fails to meet the obligations under this Agreement or under the Terms and Conditions of Use of the epost Connect system.

5.10.2 For greater certainty, the revocation or suspension of an Enrolled User to the NHP Online system does not affect the enrolment of other users enrolled in the NHP Online system, and does not terminate this Agreement, unless the Trading Partner does not replace the Primary User whose enrolment has been revoked or suspended. If the enrolment of the Primary User is revoked or suspended from the NHP Online system, the Trading Partner will replace that Primary User and will so notify the NNHPD, and will certify the name and the authority of the replacement Primary User to act on behalf of the Trading Partner.

5.10.3 The Trading Partner must inform the Primary User and Delegated User(s) of their obligation to advise the Trading Partner of the occurrence of any circumstances set out in section 5.10.1.

5.10.4 The NNHPD may of its own initiative without prior notice, or will, on request of the Trading Partner, suspend or revoke the enrolment of an Enrolled User, or remove Enrolled User access to the NHP Online system, if any of the circumstances set out in section 5.10.1 occur.

6.0 Liability and Indemnity

6.1 Exclusion of Liability

His Majesty the King in Right of Canada, Health Canada and the Minister do not assume or accept any responsibility for any claim, loss, damage or expense of the Trading Partner or any employee, agent or independent contractor of the Trading Partner arising out of the performance of this Agreement, including, without limitation, any claim, loss, damage or expense relating to personal injury, property damage, loss of profits or business revenue, or other commercial or economic losses of any kind, arising, either directly or indirectly, from the conduct of the NNHPD and whether or not any devices, test equipment, facility or personnel is furnished to the Trading Partner by NHP and howsoever caused. In no event shall the NNHPD's liability, or liability of its suppliers, licensors, contractors or agents arising out of or in connection with this Agreement exceed $50.00.

6.2 Indemnity

The Trading Partner agrees, at all times, to indemnify and save harmless, His Majesty the King in Right of Canada, Health Canada, the Minister and the NNHPD or any of His officers, servants, employees or agents from and against all claims and demands, loss, costs, damages, actions, suits or other proceedings by whomsoever made, brought or prosecuted, in any manner based upon, occasioned by or attributable to the execution of this Agreement or any action taken or things done or maintained by virtue hereof, or the exercise in any manner of rights arising hereunder, except claims for damage resulting from the negligence of any officers, servants, employees, or agents of Health Canada while acting within the scope of their duties or employment.

6.3 Force Majeure

A party shall not be liable for any loss or damage suffered by the other caused by a failure to perform any duty imposed by this Agreement where such failure is caused by an event, omission or condition not reasonably within the control of the defaulting party.

6.4 Disclaimer of Liability by the Crown

The NNHPD makes no warranties or representations, express or implied, with respect to the NHP Online system, nor to the operations which will be conducted using or relying on the NHP Online system. The NHP Online system provided by the NNHPD is provided without warranties, representations, and condition, express or implied, including, without limitation, warranties or conditions of accuracy, completeness, currency, merchantable quality, fitness for a particular purpose, or those arising by law or by statute, or by usage of trade or course of dealing.

6.5 Dispute Resolution

The Parties hereby undertake to use their best efforts to resolve in an amicable and expeditious manner any dispute or difference that may arise between them under this Agreement, first by negotiation and, failing resolution, then through an independent mediator. Any dispute or difference which has not been resolved by either of these means shall be referred to binding arbitration under the *Commercial Arbitration Act*, R.S., 1985, c.17 (2nd Supp.).

7.0 Term and Termination

7.1 Term

The term of this Agreement shall commence on the date of the last signature affixed to this agreement and shall continue until terminated in the manner set out in this Agreement.

7.2 Termination

The NNHPD may at any time terminate this Agreement, by sending a written notice, with an explanation, to the Trading Partner. The Trading Partner may at any time terminate its participation in this Agreement by sending a written notice, with an explanation, to the NNHPD.

7.3 Notice

7.3.1 Where this Agreement calls for notice or notification by either party, unless specified otherwise, such notice may be delivered by hand, by mail, by courier, by facsimile, or by epost Connect electronic communication A notice shall be deemed to have been received on the fifth business day after mailing if sent by regular mail, on the date of delivery if sent by courier and on the first business day after the date of transmission if sent by facsimile or epost Connect electronic mail.

7.3.2 Notice shall be given to the NNHPD at:

To the attention of: Stephanie Reid
Director, Health Products and Food Branch
Health Canada / Government of Canada
stephanie.reid@hc-sc.gc.ca / tel: 613-948-6279

7.3.3 Notice shall be given to the Trading Partner at:

To the attention of:

(Insert title of office, e-mail address and phone number of the Primary User)

7.4 Survival

The termination or expiration Agreement shall not affect the survival and enforceability of any provision of this Agreement which is expressly or implicitly to remain in force after such termination or expiration.

8.0 General

8.1 Invalidity of Provisions

Each of the provisions contained in this Agreement is distinct and severable and a declaration of invalidity or unenforceability of any such provision by a court of competent jurisdiction shall not affect the validity or enforceability of any other provision hereof.

8.2 Entire Agreement, Amendment and Waiver

This Agreement, including the Schedules and the Recitals, constitutes the entire agreement between the Parties pertaining to the subject matter of this Agreement. There are no warranties, representations or agreements between the Parties in connection with such subject matter except as specifically set forth or referred to in this Agreement, except as expressly provided in this Agreement. No amendment, waiver or termination of this Agreement shall be binding unless executed in writing by the party to be bound thereby. No waiver of any provision of this Agreement shall constitute a waiver of any other provision nor shall any waiver of any provision of this Agreement constitute a continuing waiver unless otherwise expressly provided.

8.3 No Partnership, Joint Venture or Agency

The Parties expressly disclaim any intention to create a partnership, joint venture or agency. It is understood, acknowledged and agreed that nothing contained in this Agreement nor any acts of the Parties shall constitute or be deemed to constitute the Parties as partners, joint venturers or principal and agent in any way or for any purpose. The Trading Partner shall not represent or hold itself out to be an agent of Health Canada. Neither Party shall have any authority to act for or to assume any obligations or responsibility on behalf of the other Party hereto. For greater certainty, neither this Agreement, nor any other document contemplated by this Agreement shall constitute or be construed or be deemed to constitute as a delegation by the Minister to the Trading Partner of any of his power, duties or functions.

8.4 Assignment

This Agreement is not assignable by the Trading Partner without the prior written consent of the NNHPD.

8.5 Conflict of Interest

No individual, for whom the post-employment provisions of the Conflict of Interest and Post-Employment Code for Public Office Holders or the Conflict of Interest and Post-Employment Code for the Public Service apply, shall derive a direct benefit from this Agreement unless that individual is in compliance with the applicable post-employment provisions.

8.6 The Trading Partner warrants:

(a) That no bribe, gift or other inducement has been paid, given, promised or offered to any person for, or with a view to, the obtaining of this Agreement by the NNHPD;

(b) and, that it has not employed any person to solicit or secure this Agreement upon any agreement for commission, percentage, brokerage or contingent fee.

8.7 Language

This Agreement is drawn in English at the request of the Parties.

8.8 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein.

In Witness Whereof

each of the Parties hereto have executed this Agreement as of the date and year stated above.

His Majesty the King in Right of Canada as represented by the Minister of Health

per:

Stephanie Reid
Director, Health Products and Food Branch
Health Canada / Government of Canada
stephanie.reid@hc-sc.gc.ca / tel: 613-948-6279

Date:

(Name of the Trading Partner)

per: _____

Legal (Registered) Name of the Trading Partner

per: _____

Primary User Name

per:

Signature

I / We have authority to bind the Trading Partner.

Date: _____

YYYY-MM-DD