Health Canada Santé Canada

FOREIGN SITE REFERENCE NUMBER AUTHORIZATION FORM
Natural Health Products Directorate

Protected when completed

Refer to the instructions before proceeding

1. Foreign Site Reference Number:	**2. Date GMP Evidence Last Updated: (to be completed by NHPD)**

A. Foreign Site:

3. Company Name:

4. Building Name:

5. Address: Please follow the sequence- Street (name and number)/ Suite/ City- Town/ Province- State/ Postal Code/ Country

6 a. Activities conducted at the above site: (check only those that apply)

	Non-Sterile	Sterile	Homeopathic
Manufacturing:	☐	☐	☐
Packaging:	☐	☐	☐
Labelling:	☐	☐	☐
Warehousing:	☐	☐	☐

6 b. Activities to be conducted for the Canadian Site indicated in part C: (check only those that apply)

	Non-Sterile	Sterile	Homeopathic
Manufacturing:	☐	☐	☐
Packaging:	☐	☐	☐
Labelling:	☐	☐	☐
Warehousing:	☐	☐	☐

The foreign site is required in Part 2, Section 28 (f) of the *Natural Health Products Regulations* (NHPR) to provide to the Minister information and documents in respect to buildings, equipment, practices and procedures used to conduct each activity specified under paragraph (b) of the NHPR, including a report from a quality assurance person demonstrating that they comply with the requirements set out in Part 3 of the NHPR.

7a. Senior Official (Foreign Site):	7b. Phone Number:	7c. Email:
8a. Quality Assurance Person (Foreign Site):	8b. Phone Number:	8c. Email:

B. Authorization:
I hereby authorize Natural Health Products Directorate (NHPD) to access the GMP information on behalf of the authorized Importer listed below. NHPD may enlist the site information on the Site License of the aforementioned Canadian importer subject to validity of the foreign site information at the time of submission.

9. Name of the Senior Official (Foreign Site): (Must be same as in Box 7a) **Signature of the Senior Official (Foreign Site):**	**Date Signed: mm/dd/yyyy**

C. Site Licence Applicant/Holder (Importer):

Importer File Number (if Known):	**Importer Company Code (if known):**
10a. Site Licence Number (**if known**)	10b. Site Licence Expiry Date (**if known**)

11. Company Name:

12. Building Name:

13. Address: Please follow the sequence- Street (name and number)/ Suite/ City- Town/ Province- State/ Postal Code/ Country

14a. Senior Official (Importer):	14b. Phone Number:	14c. Email:	14d. Fax Number:
15a. Quality Assurance Person (Importer):	15b. Phone Number:	15c. Email:	15d. Fax Number:

Canada

INSTRUCTION SHEET

PURPOSE: To facilitate the completion of the Foreign Site Reference Number Authorization Form.

This form is to be completed by a foreign site that has been issued a Foreign Site Registration Number by Health Canada and intends to provide a Canadian importer access to their good manufacturing practice (GMP) information.

BOX#	Instructions
1	Indicate the Foreign Site Registration # in this box. Refer to the Notice of Acceptance sent by NHPD, Health Canada.
2	DO NOT COMPLETE THIS BOX. This box is to be completed by the NHPD only.
3	Indicate the registered name of the foreign manufacturer, packager, and/or labeller
4	Indicate the registered name of the building (if applicable and if different from the company name).
5	Indicate the full postal address for the site where the activities **(manufacturing, packaging, labelling)** are conducted. Follow the sequence as noted in Box 5. **Note: Building refers to one location, one address. When an applicant carries out the activities in more than one building at different addresses, a new authorization form must be completed for each address.**
6a	Indicate the activity that is being performed or will be performed in this particular building i.e: manufacturing, packaging, and/or labelling. Specifically indicate if these activities relate to **non-sterile or sterile dosage forms or to Homeopathic** medicines. Note: A sterile dosage form is free from microbial contamination. Follow the guidance provided in the guidelines published by Health Canada's Health Products and Food Branch Inspectorate and Therapeutics Products Directorate. The latest version of this document is available at : www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0001-eng.php
6b	Same as in 6a but specifically indicate the information as is applicable to the Canadian Importer for whom this authorization form is being completed.
7a	A senior official must always be designated for the applicant company. The principal contact person for the licensee/applicant, at the address given, is to whom regulatory mail is sent. This is not the contact person for product application-specific questions, but the person who will represent the company. This should be a senior person in the company such as a Chief Executive Officer (CEO) or director. In some cases, especially small businesses, one person may be indicated as both the senior official and contact for this application. For each NHPD-issued company code, there must only be one associated senior official. If the senior official of the applicant company changes,

	the NHPD must be notified of this change. Refer to the Site Licence Application form (a notification submission) available on the Internet http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/index-eng.php
7b	Indicate the phone number (include extension # if applicable) of the person listed in Box 7a.
7c	Indicate the email address of the person listed in Box 7a.
8a	Indicate the representative of the foreign company who may be contacted by the NHPD with regards to Quality Assurance Activities at the site.
8b	Indicate the phone number (include extension # if applicable) of the person listed in Box 8a.
8c	Indicate the email address of the person listed in Box 8a.
9	Indicate the name and signature of the senior official responsible for all activities at the foreign site. Note: This should be the same as the name of the person indicated in Box 7a.
10a	Indicate the Site Licence number i.e. the number issued to the Canadian importer when they are approved to import natural health products into Canada. The number may be found at the top of the physical Site Licence.
10b	Indicate the expiration date of the Site Licence issued to a Canadian importer. The expiration date is located at the bottom right hand corner of the physical Site Licence.
11	Indicate the registered name of the Canadian importer who is being given authorization to access the GMP evidence for the foreign site.
12	Indicate the registered name of the Canadian importer building (if applicable and if different from the company name).
13	Indicate the full postal address for the site where the Importing activities are to be conducted. Follow the sequence as noted in Box 13. **Note: Building refers to one location, one address. When an applicant carries out the activities in more than one building at different addresses, a new authorization form must be completed for each address.**
14a	Indicate the senior official responsible for all importation activities in Canada.
14b	Indicate the phone number (include extension # if applicable) of the person indicated in Box 14a.
14c	Indicate the email address of the person indicated in Box 14a.
14d	Indicate the fax number of the person indicated in Box 14a.
15a	Indicate the name of the quality assurance person of the Canadian importer who will be contacted by the NHPD regarding questions specific to the Canadian site, roles and responsibilities.
15b	Indicate the phone number (include extension # if applicable) of the person indicated in Box 15a.
15c	Indicate the email address of the person indicated in Box 15a.
15d	Indicate the fax number of the person indicated in Box 15a