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NHP: Site Licensing Update

Recent Updates to Site Licensing and Good Manufacturing Practices Guidance Documents and Licensing Processes

The Annual CAPRA Education Day, June 16, 2016

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Presentation Outline:

Part 1: Background

Part 2: Site Licensing

- Updates to Site Licensing Guidance Document
- New 3 Stream Process and Service Standards
- Pre-Cleared Evidence and Foreign Site Reference Number
- Deficiencies and Refusal Criteria
- Renewing a Site Licence

Part 3: Good Manufacturing Practices (GMP)

- GMP Requirements: Review of 4 Key Areas
- Updates to GMP Guidance Document
- Risk Classification of NHP GMP Observations

Part 4: New QAR and SNC Forms

Part 5: Question and Answer

PART 1

Background

Part 1: Background

Natural and Non-Prescription Health Products Directorate

- Natural Health Products Directorate (NHPD) was created to administrate the *Natural Health Products Regulations*.
- In 2015 the NHPD changed its name to the Natural and Non-prescription Health Products Directorate (NNHPD) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs).
- Mission: Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.
- In May 2016 NNHPD moved to a new location:

  250 Lanark Avenue, A.L. 2002C
  Ottawa, Ontario
  K1A 0K9 (Canada Post delivery; including Xpresspost)
  K1Z 1G4 (Courier service; excluding Xpresspost)

Part 1: Background

Natural Health Products Regulations

- On January 1, 2004 The *Natural Health Products Regulations* (NHPR) came into effect
- All Canadian manufacturers, packagers, labellers, and importers of natural health products must have a site licence to conduct activities.
- Part 2 of the NHPR outlines the requirements for site licences.
- Part 3 of the NHPR outlines the requirements for good manufacturing practices.

Part 1: Background

Document Review and Updates

- In June 2014, draft documents and forms were posted for consultation
- The forms were updated incorporating feedback from stakeholders
- In December 2015, final documents and forms were posted on the Health Canada website
- NNHPD offered a series of webinars in early 2016 to present the updates on the documents and forms.

PART 2

SITE LICENSING
GUIDANCE DOCUMENT UPDATES

Part 2: Site Licensing

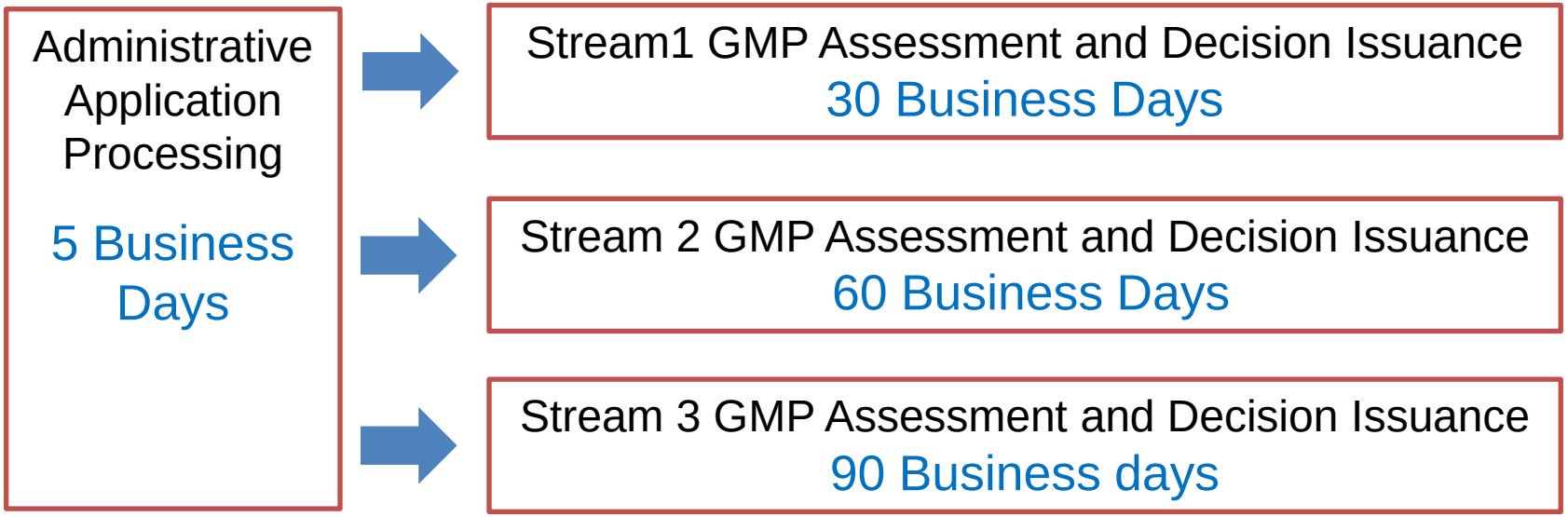
The Site Licensing Guidance Document include 4 major updates:

1. Introduce a 3 stream review approach and new service standards for site licensing
2. Introduce the concept of “Pre-Cleared GMP Evidence”
3. Description of application deficiencies
4. New guidance on the Foreign Site Reference Number (FSRN) process

Part 2: Site Licensing

New 3 Stream Process and Service Standard

- New timelines apply to applications received on or after April 1, 2016
- Applicants are encouraged to use the revised forms
- Timelines are all in business days for a total of 35, 65 and 95 business days



Please see SL Guide for Stream descriptions

Part 2: Site Licensing

Stream 1: Pre-Cleared GMP Evidence

- Pre-cleared GMP evidence allows for a quicker assessment (35 days)
- Strict timelines means applications must be complete, and only minor deficiencies will be clarified. Major deficiencies will result in refusal.
- 4 Types of Pre-Cleared GMP Evidence:
    1. Drug Establishment Licence
    2. Good Manufacturing Practices Certificate from Qualified Authority
    3. Foreign Site Reference Number (FSRN) Authorization
    4. NSF certificate (International Standard 173, Section 8 for Dietary Supplements, USFDA cGMP)
- Pre-Cleared GMP evidence is valid for 3 years with the exception of FSRN (depends on evidence type used by foreign site)
- Applicants are still required to renew their licence according to section 36 of the NHPR, however if the same piece of evidence is still valid at the time of renewal, it can be used again

Part 2: Site Licensing

Stream 2 : Applications which include 1-9 sites and include a QAR as GMP evidence for one or more sites (65 days)

Stream 3: Applications which include 10 or more sites and include a QAR as GMP evidence for one or more sites (95 days)

Note: NNHPD will strive to meet service standards for all applications, however, applicant initiated extension requests may prevent the NNHPD from being able to meet its target service standards. Thus, extensions (if granted) may result in applications being excluded from NNHPD's service standard.

Part 2: Site Licensing

Factors Affecting Screening :

- Prior to assessment the GMP evidence in the application is screened.
- The factors that will prevent the NNHPD from starting the assessment of an application include, but are not limited to, the following:
  - Supporting documents are not provided in either English or French. A translation along with the original document is acceptable.
  - No GMP evidence is provided to support a site.
  - The evidence provided is expired or records are not from within the last 12 months
- When one or more sites have valid evidence of GMPs, the assessment of those sites may proceed (if applicable). An amendment will then be required for the unassessed sites once evidence is available.

Part 2: Site Licensing

Information Requests:

- NNHPD assess GMP evidence according to the NHPR, GMP guide and the Risk Classification for NHP GMP Observations
- Applicants are expected to provide a complete application package demonstrating ability to comply with Part 3 at the time of application
- Starting May 31st NNHPD now communicates with applicants via e-post Connect. Applicants are responsible for keeping their contact information up to date and to check if they have received correspondence in order to respond within prescribed timelines.
- The NNHPD typically requests information in the form of an Information Request Notice (IRN). Up to 15 business days will be allocated to respond.
- NNHPD aims to issue 1 comprehensive IRN.
- Courtesy reminders email/phone calls for IRN response deadlines are not routinely performed.

Reminder: NNHPD no longer provides upcoming Renewal Notices and site licence holders are responsible for submitting their renewals in the prescribed timelines.

Part 2: Site Licensing

Factors Affecting Assessment:

1. Any Critical GMP Deficiencies
2. Failure to respond to an IRN request in the time allocated
3. Significantly deficient response to an IRN request
4. No activity claimed within 12 months of renewal / no available records
5. Evidence of GMP deviations that can result in or are likely to result in an immediate or latent health risk. Examples may include observations of fraud, product adulteration, misrepresentation and/or falsification of data, widespread cross-contamination, infestation, or unsanitary conditions

Any of the above may result in refusal of the application.

- NNHPD sends a notice to the applicant detailing the reasons for refusal
- Applicants may resubmit an application, once deficiencies have been addressed, which will be treated as a new application
- Request for reconsideration of NNHPD's decision to refuse is detailed in the Reconsideration Process guidance document
- Activities cannot be conducted without a valid site licence listing those activities.

Part 2: Site Licensing

Renewal Cycle

	Site Licence issued by the NNHPD (Date of Issuance)	1st Date of Renewal	2nd Date of Renewal	3rd Date of Renewal	4th Date of Renewal	5th Date of Renewal	6th Date of Renewal**	7th Date of Renewal	8th Date of Renewal
Renewal Cycle	**Jan 1, 2014**	**Jan 1, 2015**	**Jan 1, 2016**	**Jan 1, 2017**	**Jan 1, 2019**	**Jan 1, 2021**	**Jan 1, 2023**	**Jan 1, 2026**	**Jan 1, 2029**
Every year, when the licensee has held the licence less than three years from the date of issuance. Every two years, when the licensee has held the licence for a period of at least three years from the date of issuance but less than nine years. Every three years, when the licensee has held the licence for nine years from the date of issuance or more.									
GMP Evidence Required	Pre-cleared evidence or QAR for each site	Pre-cleared evidence or SNC and records for each site							

- Ensure the SL does not expire during the assessment by applying in sufficient time according to the service standards (i.e. 35, 65, or 95 business days).
- Failure to submit an application for renewal by the expiration day, will result in the SL number being cancelled.

Part 2: Site Licensing

Renewing a Site Licence

- Renewal applications may still be accepted past the expiration date, however they will be treated as a new SL application, if successful, a new SL will be issued, and the renewal cycle will re-start at a 1 year renewal cycle.
- The records required at renewal are clearly listed in the Summary of Net Changes (SNC) form. Applicants should have these ready before applying
- Companies who have not conducted activities in the 12 months prior to filing their renewal, and do not have records to demonstrate ability to comply with GMP, will be refused. Companies may reapply later once plans to start or restart activities are in place. New services standards should be considered when doing so.

Part 2: Foreign Site Reference Number (FSRN)

- A FSRN is a reference number granted to a manufacturer, packager and/or labeller that is located outside of Canada.
- The FSRN process is a service offered by Health Canada to permit Canadian importers to more efficiently demonstrate compliance with the NHP regulations.
- The FSRN is only for reference and is **not** considered an authorization or a licence to conduct activities.
- With respect to the import for sale of products, it is the responsibility of Canadian importers to demonstrate that products were manufactured, packaged, and labelled in accordance with requirements set out in the NHPR.

Benefits of FSRN

- The Importer can rely on the 35-day service standard because the FSRN is considered pre-cleared GMP evidence - quicker turn around time for assessment and decision of the application.
- The foreign site makes one application to Health Canada, rather than making an application for each importer. This saves time and resources for foreign sites working with multiple Canadian importers.

Part 2: Foreign Site Reference Number

FSRN Applications Requirements

- Foreign site submits a signed and dated FSRN application along with evidence to support GMP compliance:
  - Pre-Cleared GMP Evidence, or
  - Quality Assurance Report

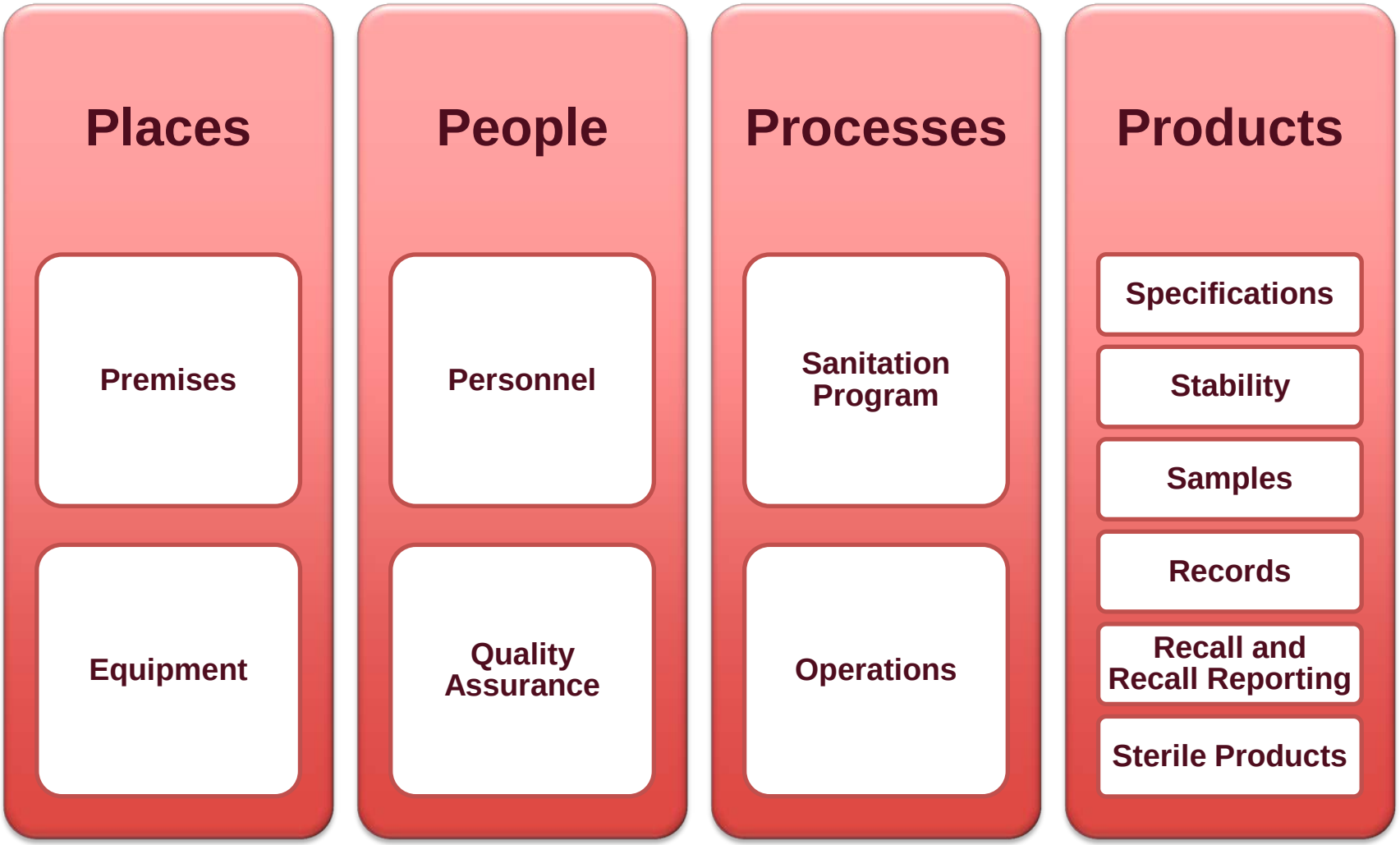
FSRN Renewal Process

- If the FSRN was issued based on Pre-Cleared GMP evidence, a renewal application will be required in 3 years
- If the FSRN was issued based on a QAR, a renewal will be required in 1 year
- Renewal applications along with GMP evidence must be submitted 35 or 65 days prior to expiry

PART 3

GOOD MANUFACTURING PRACTICES GUIDANCE DOCUMENT UPDATES

Part 3: Good Manufacturing Practices Overview



Part 3: Good Manufacturing Practices

Key Changes – GMP Guide

- Examples of evidence that would be expected to demonstrate GMPs compliance have been added and/or clarified
- Extracts of the Regulations have been reintroduced, where applicable
- Appendix 5 - Risk Classification of NHP GMP Observations has been added

Part 3: Good Manufacturing Practices

Appendix 5: Risk Classification of Natural Health Products GMP Observations

- The Risk Guide was reviewed as part of the Revised Approach to NHP Site Licensing posted in January 2014
- A tool intended to describe and standardize the risk classification of Good Manufacturing Practices (GMP) observations which can be noted during such activities as a natural health product (NHP) site licence assessment, inspection or audit.
- Can also be used by a company's quality assurance person (QAP) when conducting a GMP self-inspection.
- Aims to inform regulated parties, stakeholders and the public regarding the practices that are considered unacceptable, which may result in non-compliance with GMP and the subsequent suspension, cancellation or refusal to issue, amend or renew a NHP site licence.

Part 3: Good Manufacturing Practices

3 Risk Categories

- **Risk 1 (critical observation)**
  - A GMP deviation that results in or is likely to result in a non-compliant product or an immediate or latent health risk. This includes, but is not limited to, an observation of fraud, product adulteration, misrepresentation and/or falsification of data, or widespread cross-contamination, infestation or unsanitary conditions.
- **Risk 2 (major observation)**
  - A GMP deviation that may result in a product that does not consistently meet its marketing authorization; and/or results in a failure to follow procedures to approve batches of products prior to sale; and/or failure of the QAP to fulfil his/her responsibilities.
- **Risk 3 (other observations)**
  - A GMP deviation that does not meet Risk 1 or Risk 2 criteria but is a departure from the GMP.

Note: Repeated deviations or unresolved deviations from a previous assessment may result in a higher classification

Part 3: Good Manufacturing Practices

Examples of Risk 1 (Critical) observations:

- No quality assurance person who is responsible for assuring the quality of the product before it is released (made available) for sale;
- Products not assessed or tested according to their finished product specifications;
- Finished products that do not comply with their specifications are distributed or released for sale;
- No data, scientific rationale or program available to establish a product shelf life.

Examples of Risk 2 (Major) observations:

- Out of specification test results, deviations and/or borderline conformance not properly investigated and documented, according to a written procedure;
- Insufficient data (e.g. real time or accelerated, number of lots) to establish shelf life;
- Failure to notify Health Canada within three days of commencing the recall and provide the information as outlined in section 62 of the Regulations.

Part 3: Good Manufacturing Practices

Examples of Risk 3 (Other) observations:

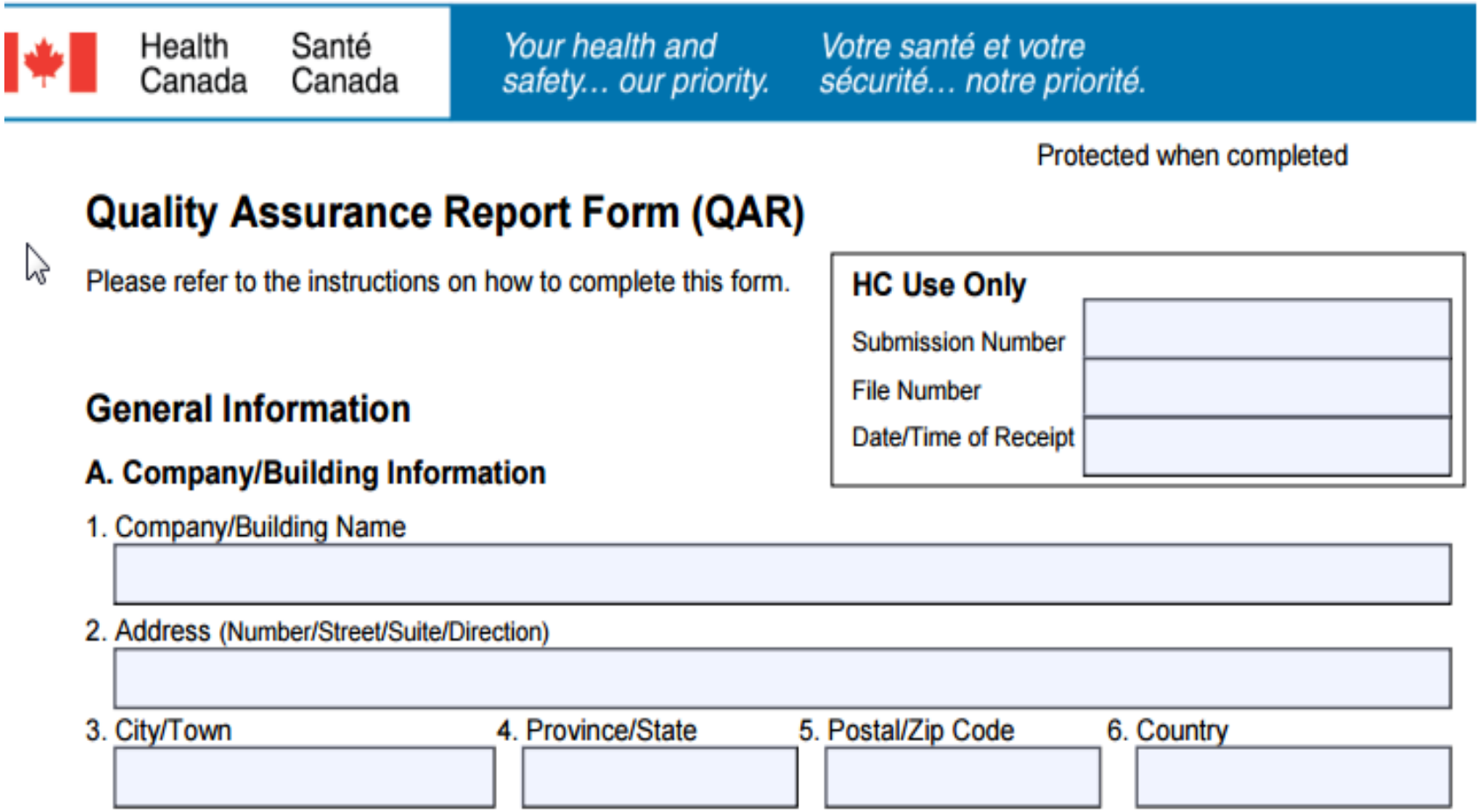
- Inadequate training records;
- Incomplete equipment and facility cleaning records;
- Failure to provide a written job description of the quality assurance person;
- Written procedures for manufacturing, packaging, labelling and storage of products are not approved by the quality assurance person;
- Insufficient quantities of product retained for complete testing;
- Absence of a recall procedure that would permit an adequate recall.

PART 4

REVIEW OF SITE LICENSING FORMS

Part 4: Review of Site Licensing Forms

Quality Assurance Report (QAR) Form



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Quality Assurance Report Form (QAR)

Please refer to the instructions on how to complete this form.

HC Use Only

Submission Number

File Number

Date/Time of Receipt

General Information

A. Company/Building Information

1. Company/Building Name

2. Address (Number/Street/Suite/Direction)

3. City/Town | 4. Province/State | 5. Postal/Zip Code | 6. Country

B. Operation(s) at this Building

7. a) Indicate the activity or activities at this building by checking the appropriate box(es)

	Non-Sterile	Sterile	Homeopathic Medicine
Manufacturing	☐	☐	☐
Packaging	☐	☐	☐
Labelling	☐	☐	☐
Importing	☐	☐	☐
Storage only	☐	☐	☐

7. b) Contract manufacturer Yes ◯ No ◯

7. c) Secondary packager (labeller) Yes ◯ No ◯

7. d) Supplementary QAR form (for homeopathic medicines only) attached? Yes ◯ No ◯

**Not required for importing activities*

8. Dosage Form(s):

Capsule ☐ Tablet ☐ Pellet ☐ Liquid ☐ Lotion ☐ Solid Extract ☐ Tincture ☐ Powder ☐

Other (specify) _____

9. Product Type(s):

Plant, alga or fungus ☐	Non-human animal material ☐	Bacterium ☐
Extracts ☐	Isolates ☐	Enzymes ☐
Vitamins ☐	Minerals ☐	Amino acids ☐
Essential fatty acids ☐	Synthetic duplicates ☐	Probiotic ☐
Homeopathic medicines ☐	Traditional medicines ☐	

C. Quality Assurance Person(s) (QAP)

10. a) Name of Quality Assurance Person who completed the QAR for this building as per Section 28(f) of the *Natural Health Products Regulations*:

10. b) In-House ◯ Third Party ◯

11. a) Name of Quality Assurance Person who is responsible for ensuring that compliance to Section 51 of the *Natural Health Products Regulations* is met:

11. b) In-House ◯ Third Party ◯

Attestation

I attest that the building(s), practice(s), and procedure(s) used for conducting activities in our facility comply with the Good Manufacturing Practices set out in Part 3 of the *Natural Health Products Regulations* (the Regulations).

Name of Quality Assurance Person	Signature of Quality Assurance Person	Date (yyyy-mm-dd)

Equipment

[Section 46 of the Regulations and Chapter 2.1.2 of the Good Manufacturing Practices guidance document]

(4) Equipment is designed, constructed, arranged, operated, and maintained in a manner that:

(a) permits effective cleaning of equipment surfaces and utensils;	Yes ◯	No ◯
(b) permits intended functioning;	Yes ◯	No ◯
(c) prevents contamination of the product; and	Yes ◯	No ◯
(d) ensures maintenance and calibration in accordance with intended use.	Yes ◯	No ◯
Records related to maintenance and calibration of equipment will be available upon request.	Yes ◯	No ◯

List SOP (titles and numbers) related to question **4**.

Quality Assurance

[Section 51 of the Regulations and Chapter 2.2.2 of the Good Manufacturing Practices guidance document]

(6) Individuals involved in manufacturing, packaging, labelling and/ or storage activities have appropriate education, training or experience demonstrated by:

(a) has a documented job description;	Yes ◯	No ◯
(b) has the appropriate training, experience and technical knowledge;	Yes ◯	No ◯
(c) approves raw, packaging and labelling materials;	Yes ◯	No ◯
(d) is responsible for methods and procedures;	Yes ◯	No ◯
(e) approves product lot or batch release for sale;	Yes ◯	No ◯
(f) approves returned product prior to release for re-sale;	Yes ◯	No ◯
(g) takes corrective actions to non-conformities; and	Yes ◯	No ◯
(h) investigates and records complaints.	Yes ◯	No ◯
Supporting documentation related to the quality assurance person responsibilities and activities will be available upon request.	Yes ◯	No ◯

List SOP (titles and numbers) related to question 6.

Provide a copy of the SOP related to quality assurance product release.

Provide a copy of a completed record related to finished product release for sale.

Operations and Recall Reporting
[Sections 50 and 62 of the Regulations and Chapter 2.3.2 & 2.4.5 of the Good Manufacturing Practices guidance document]

(9) The manufacturer and/or importer:

(a) maintains procedures to ensure the effective recall of a product; and — Yes ◯ No ◯

(b) maintains procedures to ensure that the required information, as per section 62 of the Regulations, is submitted to the appropriate HPFBI Regional Operational Centre when a recall is initiated. — Yes ◯ No ◯

List SOP (titles and numbers) related to question 9.

Provide a copy of the SOP related to recall. 

Product

Specifications

[Section 44 of the Regulations, Chapter 2.4.1 of the Good Manufacturing Practices guidance document and Chapter 1.5.3 of the Quality of Natural Health Products Guide]

(10) With respect to raw material and finished natural health product specifications:

(a) procedures are in place and followed to assess raw and/or packaging materials against written specifications;	Yes ◯ No ◯
(b) procedures are in place and followed to assess finished products against specifications for purity (microbiological and chemical contaminants);	Yes ◯ No ◯
(c) procedures are in place and followed to assess finished products for medicinal ingredient quantity and identity;	Yes ◯ No ◯
(d) procedures are in place and followed to assess finished products for potency (if applicable);	Yes ◯ No ◯
(e) procedures are in place to ensure that any change(s) in finished product specifications are reflected in the operations; and	Yes ◯ No ◯
(f) procedures are in place to ensure that every change to specifications is approved by the quality assurance person.	Yes ◯ No ◯
Product specifications and certificates of analysis will be available upon request.	Yes ◯ No ◯

If an alternate site, listed in the site licence application, is responsible for this section, please describe:

List SOP (titles and numbers) related to question 10.

Provide a copy of the SOP related to finished product specifications and testing.
Provide a copy of a completed record related to finished product testing (certificate of analysis or other finished product test record).

Stability

[Section 52 of the Regulations and Chapter 2.4.2 of the Good Manufacturing Practices guidance document]

(11) With respect to an on-going stability program, every manufacturer and/or importer has:

(a) Data demonstrating product meets specifications at expiry; Yes ◯ No ◯

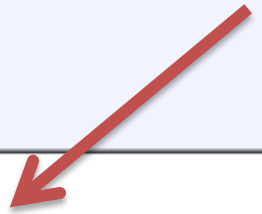
(b) Data from initial accelerated or real-time stability studies from similar products; formulations to determine the expiration date; and Yes ◯ No ◯

(c) Data from real-time stability studies to support an extended expiration date. Yes ◯ No ◯

Data related to determination of expiry date will be available upon request. Yes ◯ No ◯

If an alternate site, listed in the site licence application, is responsible for this section, please describe:

List SOP (titles and numbers) related to question 11.



Provide a copy of the SOP related to determination of expiry date.

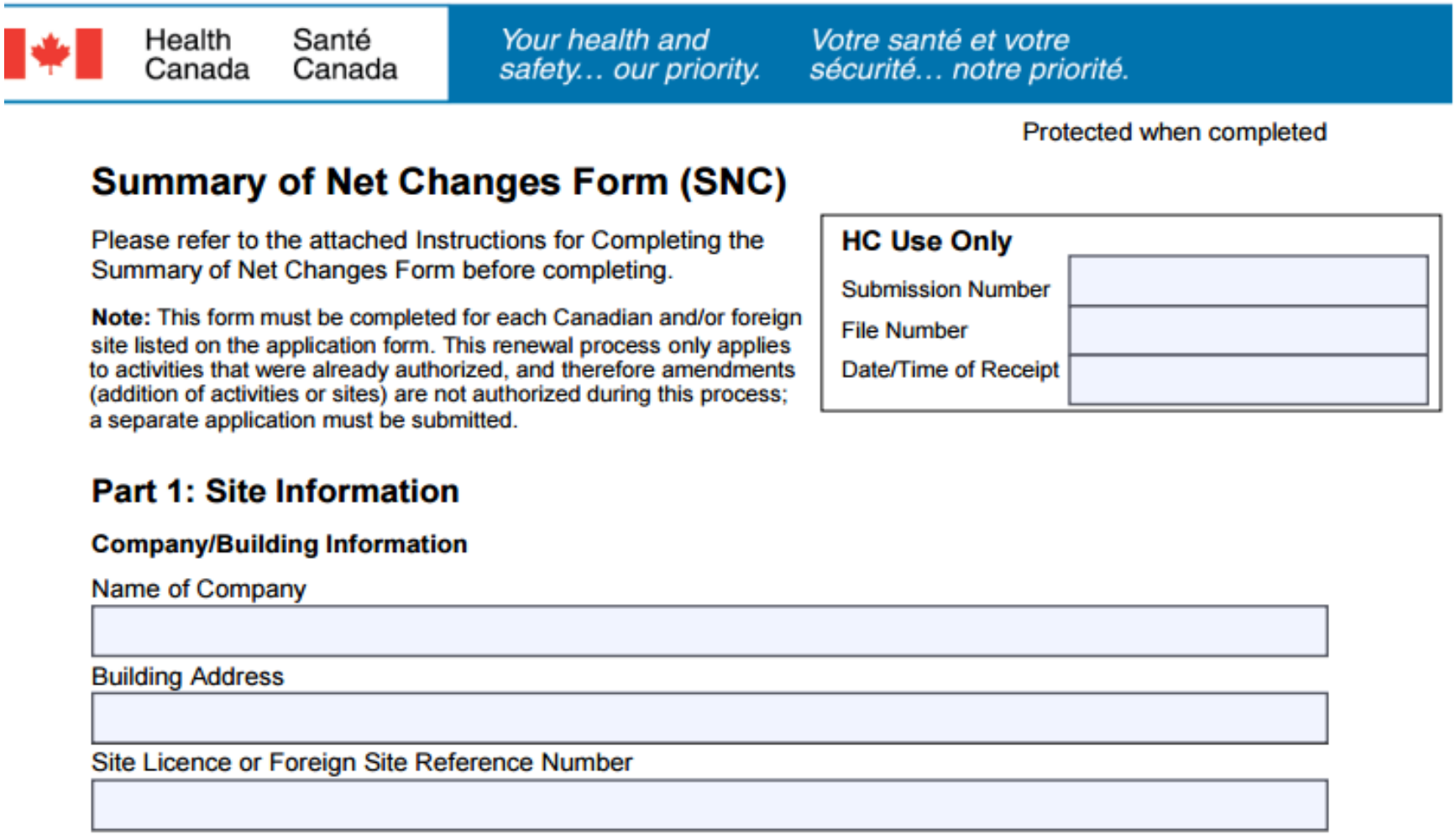
Provide a copy of a complete record of data demonstrating determination of expiry date.

List of Products Manufactured, Packaged, Labelled, Imported, and/or Stored at the Site

Product Name	Dosage Form	Product Type	Route of Administration	Natural Product Number (NPN)	Storage Conditions Requirements

Part 4: Review of Site Licensing Forms

Summary of Net Changes (SNC) Form



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Summary of Net Changes Form (SNC)

Please refer to the attached Instructions for Completing the Summary of Net Changes Form before completing.

Note: This form must be completed for each Canadian and/or foreign site listed on the application form. This renewal process only applies to activities that were already authorized, and therefore amendments (addition of activities or sites) are not authorized during this process; a separate application must be submitted.

HC Use Only

Submission Number	
File Number	
Date/Time of Receipt	

Part 1: Site Information

Company/Building Information

Name of Company

Building Address

Site Licence or Foreign Site Reference Number

Part 2: Attestation

"I hereby attest that I have knowledge of the information provided in this application for site licence renewal or foreign site reference number renewal and that the building(s), practice(s), and procedure(s) used in conducting activities in our facility comply with Good Manufacturing Practices as set out in Part 3 of the *Natural Health Products Regulations*."

Name of Quality Assurance Person	Signature of Quality Assurance Person	Date (yyyy-mm-dd)

Part 3: List of Observations and Corrective Actions with Date of Completion (if applicable)

- ○ **No observations were noted** in our last site licence cover letter or foreign site reference number notice of acceptance issued by the NNHPD. (If checked, please proceed to part 4.)
- ○ **Observation(s) were noted** in our last site licence cover letter or foreign site reference number notice of acceptance issued by the NNHPD. (If checked, please complete the table below.)

Observation(s)	Corrective Action(s) Taken	Date(s) of Completion

Part 4: Summary of Net Changes and Description

- ○ **There have been no changes** to the building(s), practice(s), and procedure(s) used in conducting activities in our facility, from the information supplied in our previous site licence or renewal application in support of GMP compliance, as per Part 3 of the Natural Health Products Regulations (the Regulations). (If checked, please complete Parts 5 and 6.)
- ○ **There have been changes** to the building(s), practice(s), and procedure(s) used in conducting activities in our facility from the information supplied in our previous site licence or renewal application in support of GMP compliance, as per Part 3 of the Regulations. (If checked, please identify the change(s) by checking the appropriate box(es) in the Summary of Net Changes Table (below) and submit a detailed description by completing the relevant section(s) of the QAR form or by providing another form of acceptable GMP evidence to support the change(s)). Then complete Parts 5 and 6.

Summary of Net Changes Table (Check if applicable)

GMP Categories	GMP Sub Categories	Sections of NHPR	QAR Questions	SQAR Questions
Places	☐ Premises	45	1-3	1
	☐ Equipment	46	4	2
People	☐ Personnel	47	5	3
	☐ Quality Assurance	51	6	N/A
Processes	☐ Sanitation Program	48	7	4
	☐ Operations	49	8	5
	☐ Operations - Recall	50 & 62	9	N/A
Products	☐ Specifications	44	10	6
	☐ Stability	52	11	7
	☐ Samples	61	12	N/A
	☐ Records	53-58	13	N/A
	☐ Sterile Products	59 & 60	14	N/A

Part 5: Records (Please provide records dated from within the last 12 months)

Record	Check Box	Record Type	Relevant Section(s) of Part 3 of NHPR	Instructions	Example of Acceptable Record Types
1	☐	Storage Controls	45(2)	Supply records demonstrating that natural health products (NHPs) are stored under conditions that maintain quality and safety.	Data logs recording temperature, humidity, and light controls
2	☐	Pest Control	45*(d,e)*	Supply records demonstrating that NHPs are manufactured, packaged, labeled and stored in premises that are maintained in a manner that prevents the contamination of the products.	Contractor pest control invoice, internal pest activity inspections logs
3	☐	Personnel Training	47	Supply records demonstrating that NHPs are manufactured, packaged, labeled and stored by personnel that are qualified by education, training or experience to perform their respective tasks.	Certificates or data logs (with trainee signature) of on-going GMP training (internal or external)
4	☐	Sanitation	46*(a)*, 48	Supply records demonstrating that NHPs are manufactured, packaged, labeled and stored in compliance with a sanitation program.	Data logs of site/facility cleaning and equipment cleaning (include schedules and frequencies)
5	☐	Finished Product Testing	44(1,2), 51(4)	Supply: • Records demonstrating that every NHP complies with its specifications with respect to medicinal ingredients, identity, quantity and potency if applicable, and product purity (a record of full testing for one NHP). **Note:** Importers may provide records of testing conducted by the manufacturer • Records of raw material testing only if it is part of the finished product specifications.	Certificate of analysis (CoA), batch records of finished products and raw materials, if applicable
6	☐	Quality Assurance and Product Release	51	Supply records demonstrating that every lot or batch of NHPs has been approved by a quality assurance person before being made available for sale.	Finished product release record or release certificate
7	☐	Product recall Procedure	50, 62	Supply records demonstrating that the manufacturer, packager, labeller and/or importer have an established system of control that permits the rapid and complete recall of every lot or batch of the NHP that has been made available for sale.	Product recall record; or confirmation of no recall for the past 12 months
8	☐	Stability	52, 53*(g)*, 56*(e)*	Supply: • Records demonstrating that every NHP complies with its specifications until its determined expiry date. • Record of stability data (complete or ongoing).	Data logs from accelerated or real-time stability studies (must show product meets its label claim at time of expiry)

Part 6: List of Products Manufactured (M), Packaged (P), Labelled (L), Imported (I), and/or Stored at the Site

Product Name	Dosage Form	Product Type	Route of Administration	Natural Product Number (NPN)	Storage Conditions Requirements

Communicating with the NNHPD

- Submitting Site Licence Applications:
  - Secure Email – e-post Connect
  - CD or DVD
  - Paper Format – Mail

- Ensure electronic submissions contain files named with a minimum number of characters, all files are consolidated into a zip file and are placed into relevant order. For example, site1_Q1a.pdf

- **NNHPD began using epost Connect, as the primary tool for communicating with applicants electronically, on May 30, 2016.**
  epost Connect™ is the digital delivery platform with bank-grade encryption that facilitates the sending and receiving of confidential messages and documents with one or multiple recipients. For more information on epost Connect ™ and to enroll visit:
  http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/trading_part_commerce-eng.php

- General Inquiries : NNHPD_DPSNSO@hc-sc.gc.ca

References

- Revised Approach:

http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/consult_rev-app-licence-eng.php

- RSS Feed:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/feeds-fils/index-eng.php

- Trading Partner guidance:

http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/trading_part_commerce-eng.php

- Link to new guides and forms:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/docs-eng.php

- SL / FSRN Holder list:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/sl-list-le-eng.php

- ePost Connect – Frequently Asked Questions

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/online-enligne/questions-eng.php

PART 5

QUESTIONS AND ANSWERS