Protected when completed

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