Health Canada Santé Canada

CLINICAL TRIAL APPLICATION AND ATTESTATION FORM
Natural Health Products Directorate

HC USE ONLY		
File Number	Submission Number	Date/Time of Receipt

Please refer to the *Clinical Trial Guidance Document* for help **Please print clearly** *Denotes mandatory

Part 1: Applicant and Contact Information

A. Sponsor

Individual/Company/Institution/Organization (Full Name – No Abbreviations)*			Company Code (if known)
Street / Suite / PO Box*			
City / Town*	Province / State*	Country*	Postal / ZIP Code*

Contact Information of Sponsor (if Sponsor is an individual) or Senior Official (if Sponsor is a company, institution, or organization)

Name ☐ Mr. ☐ Ms. ☐ Dr.	Surname*	Given Name*
Title*	Language Preferred ☐ English ☐ French	
Telephone No.*	Fax No.	E-mail

B. Contact for this Application

☐ Same as A

Name ☐ Mr. ☐ Ms. ☐ Dr.	Surname*	Given Name*
Title*	Language Preferred ☐ English ☐ French	
Company Name (Full Name – No Abbreviations)*		**Address same as Sponsor** ☐
Street / Suite / PO Box*		
City / Town*	Province / State*	Country*	Postal / ZIP Code*
Telephone No.*	Fax No.	E-mail

C. Representative in Canada (must be completed if Sponsor is located outside Canada)

☐ Same as B ☐ Not applicable

Name ☐ Mr. ☐ Ms. ☐ Dr.	Surname*	Given Name*
Title*	Language Preferred ☐ English ☐ French	
Company Name (Full Name – No Abbreviations)*		
Street / Suite / PO Box*		
City / Town*	Province / State*	Country*	Postal / ZIP Code*
Telephone No.*	Fax No.	E-mail

Canada

Part 2: Research Ethics Board(s)

A. Research Ethics Board(s) that APPROVED the protocol*

☐ Includes member knowledgeable in complementary or alternative health care (identify member and expertise in the cover letter) *

Research Ethics Board Attestation enclosed?

☐ Yes
☐ Approval not obtained at this time (Research Ethics Board Attestation must be submitted prior to commencement of the trial)

B. Research Ethics Board(s) that REFUSED the protocol*

Information regarding Research Ethics Board(s) that have refused to approve the protocol enclosed?

☐ Yes
☐ Not applicable
☐ Refusals not known at this time

Part 3: Clinical Trial Application Information

A. Clinical Trial Application (CTA)

†pharmaceutical, biologic, or medical device must be used according to its approved conditions of use

Indicate the type of application (select one or more):

☐ Phase I-Bioequivalency ☐ Phase I-Healthy Subjects ☐ Phase I-Other ☐ Phase II ☐ Phase III
☐ NHP + Pharmaceutical† ☐ NHP + Biologic† ☐ NHP + Medical Device†
☐ CTA Amendment (go to part 4)

Protocol # (if known)	Protocol Title

B. Reference Submission

☐ Not applicable

If other submission(s) that contains the evidence to support the safety, efficacy and/or quality of the NHP to be used in the clinical trial are referenced in this application, the following information must be provided:

Submission / NHP-MF # NPN / DIN / DIN-HM #

Letter of Access is enclosed? ☐ Yes ☐ Not applicable

C. Content of Application*

†must be submitted in electronic format, in addition to hard copy
‡if unavailable at this time, must be provided prior to commencement of the trial

Confirm, by checking the boxes below, that all application components have been provided. Include, in the cover letter, a brief rationale explaining why any required component of the application has not been provided. All required components of the application must be submitted in hard copy.

Number of diskettes / CDs:

☐ Cover letter
☐ Table of contents
☐ Investigator's Brochure†
☐ Protocol Synopsis & Evaluation Review Template†
☐ Protocol†
☐ Informed Consent Form
☐ Quality Overall Summary – NHP Template†
☐ Quality Data
☐ Product Monograph (if available)
☐ Approved Label (if available)
☐ Information regarding refusals by other regulatory authorities or Research Ethics Boards outside Canada (if applicable)
☐ Clinical Trial Application and Attestation Form ('attestation' signed by the Senior Officials)
☐ Clinical Trial Site Information Form‡
☐ Research Ethics Board Attestation form for each site‡
☐ Qualified Investigator Undertaking form‡
☐ Designated Party Authorization Form (if applicable)
☐ Animal Tissue Form(s) (if applicable)
☐ Authorization for a Third Party to Import an NHP form (if applicable)
☐ Letters of Access (if applicable)

Part 4: Clinical Trial Application – Amendment

☐ Not applicable

A. Reference Submission*

Please provide the submission number of the approved CTA to which changes will be made.

CTA Submission #

Protocol # (if known)	Protocol Title

B. Content of Amendment*

Indicate the type of change(s) to the approved CTA (select one or more) and provide the revised documents, as well as a cover letter outlining the changes made and the reason(s) for the changes.

- ☐ Cover letter
- ☐ Clinical Trial Application and Attestation Form ('attestation' signed by the Senior Officials)
- ☐ Dosage regimen (dose, frequency, quantity per dosage unit, potency, and/or duration of use) within established safety range
- ☐ Comparator
- ☐ Placebo (substitution)
- ☐ Risk information
- ☐ Protocol
- ☐ Investigator's Brochure
- ☐ Informed Consent Form
- ☐ Other changes affecting safety or efficacy (specify):
- ☐ Source material of any of the medicinal ingredients
- ☐ Specifications
- ☐ Changes to or from synthetically manufactured medicinal ingredient
- ☐ Manufacturing information
- ☐ Dosage formulation
- ☐ Addition or substitution of a non-medicinal ingredient not on the NHPD List of Acceptable Non-medicinal Ingredients
- ☐ Animal Tissue Form(s)
- ☐ Other changes affecting quality (specify):

Part 5: Clinical Trial Site Information

A. Clinical Trial Site*

Clinical Trial Site Information Form enclosed for all sites?

☐ Yes ☐ No ☐ Site information not known at this time

(Clinical Trial Site Information Form must be submitted prior to commencement of the trial at each site)

B. Qualified Investigator*

Qualified Investigator Undertaking form enclosed for all sites? (There must be only one Qualified Investigator for each clinical trial site)

☐ Yes ☐ No ☐ Qualified Investigator not known at this time

(Qualified Investigator Undertaking form must be submitted prior to commencement of the trial at each site)

Part 6: Study Product Information

(copy sections 1A-C if more than one NHP is to be studied, copy sections 1A-B/2 if more than 10 ingredients are contained in the NHP/placebo)

Primary Brand Name / Product Code*	Other(s) if any

Was animal tissue used in the processing of the NHP or the placebo, although not present in the final product? If yes, complete Animal Tissue Form. ☐ Yes ☐ No

1A: Medicinal Ingredient(s) of the NHP

Ingredient No.	A Standard or Grade	B Scientific Monograph		C* Proper Name	D Common Name	E* Quantity per dosage unit	F* Synthetic		G** Animal Tissue	
		Yes	No				Yes	No	Yes	No
1.		☐	☐				☐	☐	☐	☐
2.		☐	☐				☐	☐	☐	☐
3.		☐	☐				☐	☐	☐	☐
4.		☐	☐				☐	☐	☐	☐
5.		☐	☐				☐	☐	☐	☐
6.		☐	☐				☐	☐	☐	☐
7.		☐	☐				☐	☐	☐	☐
8.		☐	☐				☐	☐	☐	☐
9.		☐	☐				☐	☐	☐	☐
10.		☐	☐				☐	☐	☐	☐

**if yes, complete Animal Tissue Form

Ingredient No.	H Potency (if applicable)		I* Source (if more than one enter on new line within the same cell)		J Extract (if applicable)		K Method of preparation
	Amount	Constituent	Proper Name	Material	Ratio	Quantity Dried Equivalent	
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

1B: Non-medicinal Ingredient(s) of the NHP					
Ingredient No.	Proper Name	Common Name *	Purpose *	Animal Tissue Used **	
				Yes	No
1.				☐	☐
2.				☐	☐
3.				☐	☐
4.				☐	☐
5.				☐	☐
6.				☐	☐
7.				☐	☐
8.				☐	☐
9.				☐	☐
10.				☐	☐

** if yes, complete Animal Tissue Form

Ingredient No.	Standard or Grade	Source (if more than one enter on new line within the same cell)	
		Proper Name	Material
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

1C: Proposed Conditions of Use of the NHP According to Protocol			
Proposed Use or Purpose *			
Dosage Form*	Duration of Use*	Sterile* ☐ Yes ☐ No	Route of Administration*

Proposed Dose

Treatment Group*	Amount to Be Taken at One Time		Frequency*	Directions of Use*
	No. of Dosage Units* (e.g. 1, 2, 3…)	Dosage Unit* (e.g. capsule, mL, tsp)		

Risk Information

Cautions and Warnings*
Contraindications*
Known Adverse Reactions*

2: Placebo Ingredients

Ingredient No.	Standard or Grade	Scientific Monograph		Proper Name*	Common Name	Quantity per dosage unit	Synthetic*		Animal Tissue Used**	
		Yes	No				Yes	No	Yes	No
1.		☐	☐				☐	☐	☐	☐
2.		☐	☐				☐	☐	☐	☐
3.		☐	☐				☐	☐	☐	☐
4.		☐	☐				☐	☐	☐	☐
5.		☐	☐				☐	☐	☐	☐
6.		☐	☐				☐	☐	☐	☐
7.		☐	☐				☐	☐	☐	☐
8.		☐	☐				☐	☐	☐	☐
9.		☐	☐				☐	☐	☐	☐
10.		☐	☐				☐	☐	☐	☐

**** if yes, complete Animal Tissue Form**

Ingredient No.	Potency (if applicable)		Source (if more than one enter on new line within the same cell)*		Extract (if applicable)		Method of preparation
	Amount	Constituent	Proper Name	Material	Ratio	Quantity Dried Equivalent	
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

I, the undersigned, certify that the information and material included in this clinical trial application is accurate and complete[1].

Name of Authorized Signing Official (print)	Signature	Date (yyyy / mm / dd)
Title	Telephone No.	Fax No.
Name of Company to which the Authorized Signing Official Belongs		

[1] If the signing official is a third party acting on behalf of the Sponsor identified in Part 1, the Designated Party Authorization Form must be signed by the Sponsor and filed with the complete application.

Part 7: Clinical Trial Attestation

In regard to the clinical trial that is the subject of this application, I attest that:

a) All information contained in, or referenced by, this application is complete and accurate and is not false or misleading.

b) The clinical trial will be conducted in accordance with the protocol and the requirements as set out in Part 4 of the *Natural Health Products Regulations.* The clinical trial will be conducted according to Good Clinical Practices.

c) All changes to clinical trials will be reported to the Natural Health Products Directorate, and all reporting requirements will be met, as specified in Part 4 of the *Natural Health Products Regulations*.

d) The trial WILL NOT commence at any site until receipt of a Notice of Authorization from the Natural Health Products Directorate and until the approval of Research Ethics Board(s) is obtained.

e) Records will be maintained for a period of 25 years and will be accessible for on-site inspection by Health Canada inspectors.

Name of Senior Medical Officer or Scientific Officer in Canada (print)*	Signature*	
Telephone No.	E-mail	Date (yyyy / mm / dd)
Name of Senior Executive Officer or Department Head (print)*	Signature*	
Telephone No.	E-mail	Date (yyyy / mm / dd)

Please submit CTAs and CTA-Amendments directly to:

Health Canada, Health Products & Food Branch
Natural Health Products Directorate
Bureau of Product Review & Assessment
Submission Management Division
Attention: Clinical Trial Unit
Qualicum Tower A
2936 Baseline Rd. AL: 3300B
Ottawa, ON
K1A 0K9
(For courier delivery: K2H 1B3)