



**NATURAL HEALTH PRODUCT LIABILITY INSURANCE APPLICATION**

CANADA \$ \_\_\_\_\_ U.S. \$ \_\_\_\_\_ ALL OTHER (please list countries):  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_

2) In \$CDN, what were your anticipated gross revenues for the next twelve (12) months or your next fiscal year? (If using fiscal year, please specify your fiscal year-end \_\_\_\_\_.)

CANADA \$ \_\_\_\_\_ U.S. \$ \_\_\_\_\_ ALL OTHER (please list countries):  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_

**3. PRODUCT INFORMATION**

A) Please list your Company's products and indicate whether you are the manufacturer or distributor. If you are the manufacturer, please indicate whether you manufacture the entire product or only a part of it. For distributed products, please indicate the product's country of origin. If many products, please attach your product catalogue.

PRODUCT	% OF TOTAL REVENUE	MANUFACTURER OR DISTRIBUTOR	WHOLE OR PART	COUNTRY OF ORIGIN

(attach list if necessary)

For all products for which you are a distributor, do you receive a certificate of products liability insurance from the manufacturer?  YES  NO

If YES, is the limit of insurance carried by the manufacturer, at least equal to the products liability limit you carry or are requesting?  YES  NO

Are you added to the manufacturer's policy as an additional insured?  YES  NO  
 If YES, please attach a current copy of this endorsement.

B) What is the total number of products that your Company manufactures/distributes? \_\_\_\_\_

How many different product lines does this represent? \_\_\_\_\_

Are your products required to meet the regulatory requirements as stipulated by the appropriate regulatory authority in?

Canada  YES  NO U.S.  YES  NO

Other countries  YES  NO (If YES, please list each country) \_\_\_\_\_

If NO, please explain and attach documentation either indicating why any product is not required to meet any regulatory requirement(s) or when such product, as required by law, will meet such regulatory requirements?  
 \_\_\_\_\_

C) Please attach a legible copy of the current labeling used for each product.

D) Do any of your products contain the following (including any derivative thereof): Androsteredione, animal derived products, Aristolochic Acid, Butanediol, Chaparral, Chomper, Comfrey, Creatine, Dehydroepiandrosterone, Dieter's Tea, Diethylstilbestrol, Ephedrine, Estazolam, Gamma Butyrolactone, Gamma Hydroxybutyric Acid, Germander, Germanium, Indinavire, Jin Bu Huan, L-tryptophan, Melatonin, oral contraceptives, Phentermine, Phenylalanine, Phenylpropanolamine (PPA), products that are know mutagens, products that are known teratogens, psychotropic products, St. John's Wort, Stephania or Magnolia, Thimerosal, Tiractricol, Trix Metabolic Accelerator, vaccines, weight reduction products, Willow Bark, and Yohimbe (if yes, please explain).

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E) Are any products that you manufacture or distribute, sold or marketed as a weight management product? (Weight management being defined as either weight gain/bulking or weight loss.)  YES  NO

If YES, please list each product separately and indicate revenues for each product. \_\_\_\_\_

F) Are any products manufactured or sold under labels of others?  YES  NO  
If YES, please complete section 6 (Contract Manufacturing)

G) Please complete the following revenue projection for your next twelve (12) months (in \$CDN):

PRODUCT	CANADIAN REVENUE	U.S. REVENUE	OTHER REVENUE
Controlled Drugs			
Hormones/Steroids			
Vaccines			
Prescriptions			
Over the counter			
Food Supplements/Vitamins			
Natural Products			
Cosmetics			
Other (please attach list of products):			
TOTAL			

H) Does your Company plan to introduce any new product(s) and/or service(s) within the next twelve (12) months?  YES  NO

If YES, please list and describe: \_\_\_\_\_

I) Are any of your Company's products required to be sold sterile?  YES  NO  
If YES, please indicate if your Company or a third party sterilizes the product. Please identify the third party:

\_\_\_\_\_

Is your Company being held harmless in those instances where the product sterilization has been subcontracted out?  YES  NO

If NO, why not? \_\_\_\_\_

J) Have any of your Company's products for any reason been recalled, discontinued or withdrawn from the market?  YES  NO

If YES, please provide full details including the date, products involved, reason for the recall, discontinuation or withdrawal and the outcome (attach separate sheet if necessary): \_\_\_\_\_

K) Have any of your Company's products ever been subject to an inquiry or been investigated by any regulatory authority?  YES  NO

If YES, please provide full details including the date, products involved, reason for the investigation or inquiry and the outcome (attach separate sheet if necessary): \_\_\_\_\_

L) Have any of your Company's products been the subject to any regulatory authority warning(s) or advisory(ies)?  YES  NO

If YES, please advise full details: \_\_\_\_\_

**4. RISK MANAGEMENT PRACTICES**

A) Is your Company currently in compliance with all applicable government regulations?  YES  NO  
If NO, please provide a copy of the compliance report and all applicable correspondence.  
Please indicate when will your Company be in compliance: \_\_\_\_\_

B) Does your Company have a written quality control program?  YES  NO  
If YES, please advise the most recent revision date: \_\_\_\_\_  
If NO, when will one be implemented? \_\_\_\_\_

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- C) Does your Company have a formal product recall program in place?  YES  NO  
 If YES, please advise the most recent revision date: \_\_\_\_\_  
 If NO, when will one be implemented? \_\_\_\_\_
- D) Does your Company maintain a written record of incident reports and/or complaints?  YES  NO  
 If YES, who in your Company is responsible for these matters? \_\_\_\_\_  
 If NO, why are written records not maintained? \_\_\_\_\_
- E) Does your Company follow Good Manufacturing Practices (GMP)?  YES  NO  
 Are you ISO registered?  YES  NO  
 If YES, what level? \_\_\_\_\_
- F) Does your Company maintain samples of its product(s)?  YES  NO  
 If YES, for how long are they retained? \_\_\_\_\_  
 Who, in your Company, is required to maintain these samples? \_\_\_\_\_
- G) Are any materials or products handled by your Company hazardous, either by themselves or in combination with other materials?  YES  NO  
 If YES, please advise which materials/products and how they are contained: \_\_\_\_\_
- H) Does your Company have live viruses on its premises?  YES  NO  
 If YES, please identify the viruses and advise how they are contained: \_\_\_\_\_
- I) Does your Company have a license or governmental authority to keep live viruses?  YES  NO  
 If YES, please confirm license number and/or advise who the regulating authority is: \_\_\_\_\_

- J) Does your Company consult with legal counsel for issues concerning the following:
- |                       |                              |                             |   |
|-----------------------|------------------------------|-----------------------------|---|
| Contractual Liability | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Product Labeling      | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Package Inserts       | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Product Guarantees    | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Promotional Materials | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Instruction Manuals   | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |

- K) Does your Company keep laboratory animals on the premises?  YES  NO  
 If YES, please indicate type of animals, their numbers, and purpose.

ANIMAL	NUMBER	PURPOSE

**5. CLINICAL TRIALS \*For each clinical trial a copy of the Protocol and the Informed Consent must be attached.**

**Does your Company require coverage for Clinical Trials?**  YES  NO  
**If YES, please complete a CLINICAL TRIALS APPLICATION for each trial.**  
**If NO, please proceed to Section 7 (PREVIOUS INSURANCE).**

- A) Has the proposed clinical trial(s) been approved by the appropriate government authority(ies)?  YES  NO  
 If NO, please provide details: \_\_\_\_\_
- B) Are all trial participants required to sign an informed consent form?  YES  NO  
 If NO, please explain why not? \_\_\_\_\_
- C) Will your Company be conducting the clinical trial(s)?  YES  NO  
 If NO, please identify who has been contracted to conduct the trial(s) on your Company's behalf and provide details of any hold harmless/indemnification agreements: \_\_\_\_\_
- D) Who will be the principal investigator(s) in the clinical trial(s)? \_\_\_\_\_
- E) Do any of your Company's researchers own or have stock in the Company?  YES  NO

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If YES, please list and advise percentage (%) of ownership: \_\_\_\_\_

F) Within the next twelve (12) months, is your Company planning to manufacture any product(s) currently under investigation?  YES  NO  
If YES, please list and provide details: \_\_\_\_\_

G) Within the next twelve (12) months, does your Company plan to sell any of its research conclusions to others?  YES  NO  
If YES, please provide details: \_\_\_\_\_

# CLINICAL TRIAL QUESTIONNAIRE

(Please complete a separate questionnaire for each trial)

Protocol Title: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Trial Phase: Phase I:  Phase II:  Phase III:  Phase IV:  OTHER: \_\_\_\_\_

Number of sites: CANADA: \_\_\_\_\_ OTHER: \_\_\_\_\_  
(for Other, please list all countries)

Number of subjects: CANADA: \_\_\_\_\_ U.S.: \_\_\_\_\_ OTHER: \_\_\_\_\_

Please indicate the anticipated number of patients to be enrolled/dosed in the next twelve (12) months:  
CANADA: \_\_\_\_\_ U.S.: \_\_\_\_\_ OTHER: \_\_\_\_\_

What date will you begin enrolling patients? \_\_\_\_\_

What date will you begin dosing patients? \_\_\_\_\_

What is the duration of a patient's participation? \_\_\_\_\_

What is the expected completion date of this trial? \_\_\_\_\_

Please describe the purpose of this clinical investigation: \_\_\_\_\_

Please list known side effects of this product: \_\_\_\_\_

Please provide a copy of the final testing, protocol, informed consent forms, any hold harmless/indemnification agreements.

**6. CONTRACT MANUFACTURERS' ADDENDUM**  
**(If not performing any contract manufacturing services, proceed to Section 7 – Previous Insurance.)**

With respect to the product(s) your Company is manufacturing for others, please answer the following questions:

A) Please indicate the percentage (%) of products made to the specifications of others: \_\_\_\_\_ %

B) Please indicate the percentage (%) of products made to your Company's own specifications: \_\_\_\_\_ %

C) Does your Company manufacture and/or assemble the final product(s)?  YES  NO  
If NO, please explain: \_\_\_\_\_

D) Does your Company require signed final acceptance from its customers?  YES  NO  
If NO, please explain: \_\_\_\_\_

E) Which of the following services does your Company provide:

- Research and development:  YES  NO
- Regulatory consulting:  YES  NO
- In-house design and prototyping:  YES  NO
- Engineering:  YES  NO
- Product labeling:  YES  NO
- Packaging validation:  YES  NO
- Material supply and management:  YES  NO
- Inventory management:  YES  NO
- Warehousing:  YES  NO

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End-user shipping:  YES  NO  
 Logistics management:  YES  NO  
 Sales and marketing:  YES  NO  
 Other (please specify): \_\_\_\_\_

F) Please list your Company's five (5) largest customers and provide a description of services being offered including the total revenue derived from each:

CUSTOMER NAME	DESCRIPTION OF SERVICES	TOTAL REVENUE
1)		
2)		
3)		
4)		
5)		

**7. PREVIOUS INSURANCE**

A) Is your Company currently insured under a Products Liability policy?  YES  NO  
 If YES, please complete the following:

Insurer: \_\_\_\_\_ Policy Period: \_\_\_\_\_  
 Policy Number: \_\_\_\_\_ Limit of Liability: \_\_\_\_\_

B) During the last five (5) years, has your Company carried Products Liability insurance?  YES  NO  
 If YES, please complete the following for all previous Products Liability policies:

INSURER	TERM	LIMIT	DEDUCTIBLE	PREMIUM

C) Is this policy written on a claims made form?  YES  NO  
 If YES, what is the current retroactive date shown on your policy? \_\_\_\_\_

Has a continuous claims made policy been in force since this date?  YES  NO

D) Has your Company, its partners, directors or officers ever been declined, non-renewed or cancelled by any Insurer for Products Liability insurance?  YES  NO  
 If YES, please explain: \_\_\_\_\_

**8. CLAIMS INFORMATION**

A) Has your Company, its partners, directors, officers or employees ever had a written demand or civil proceedings for compensatory damages made against them?  YES  NO  
 If YES, please provide the following details on a separate sheet:

- 1) Date of claim
- 2) Claimant's name
- 3) Nature of claim
- 4) Amount of indemnity payment and amount of defense costs
- 5) Final dispositions or current status of claim

B) Is your Company, its partners, directors, officers or employees aware of any job disputes or fee disputes during the last five (5) years?  YES  NO  
 If YES, please describe in detail: \_\_\_\_\_

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C) Is your Company, its partners, directors, officers or employees aware of any other fact, situation or circumstance that may result in a written demand or civil proceedings for compensatory damages?  YES  NO  
If YES, please describe in detail: \_\_\_\_\_

Without limitation of any other remedy available to the Insurer, it is hereby agreed that if there be knowledge of any of the matters described in Section 8, any written demand or civil proceedings for compensatory damages subsequently emanating therefrom is excluded from coverage under the proposed insurance.

**9. NOTICE CONCERNING PERSONAL INFORMATION**

By purchasing insurance from Creechurch International Underwriters Ltd. (Creechurch), a customer provides Creechurch with his or her consent to the collection, use and disclosure of personal information, including that previously collected, for the following purposes:

- the communication with underwriters;
- the underwriting of policies;
- the evaluation of claims;
- the detection and prevention of fraud;
- the analysis of business results;
- purposes required or authorized by law.

For the purposes identified above, personal information may be disclosed to Creechurch's related or affiliated companies and service providers.

Further information about Creechurch's personal information protection policy may be obtained by contacting their privacy officer at 416-601-2155.

**10. WARRANTY STATEMENT**

The undersigned warrants that to the best of his or her knowledge, the statements set forth in this Application are true. The undersigned also warrants that they have not suppressed or misstated any material facts.

If the information provided in this Application should change between the date of the Application and the effective date of the policy, the undersigned warrants he or she will immediately report such changes to the Insurer.

Signing of this Application does not bind the undersigned to purchase this insurance, nor does it bind the Insurer to complete this insurance. However, should the Insurer bind and issue a policy, this Application shall serve as the basis of such contract and will be attached to and form part of the policy.

**QUEBEC RESIDENTS ONLY:**

I hereby confirm my request that the present document and any other document and correspondence pertaining to the present insurance be in the English language.

SIGNED: \_\_\_\_\_  
(Authorized Representative)

DATED: \_\_\_\_\_

NAME (Please Print): \_\_\_\_\_

TITLE/POSITION: \_\_\_\_\_