

PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

2) Estimated Gross Revenues for your next twelve (12) months or your next fiscal year (\$CDN):

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

E) Your Company is engaged in:

OPERATIONS	LAST TWELVE (12) MONTHS			NEXT TWELVE (12) MONTHS		
	Canada	U.S.	Other	Canada	U.S.	Other
Manufacturing:						
Distributing:						
Retailing:						
Research (for others):						
Other (please specify):						
TOTAL: (must equal figures in 2 above)						

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) Are any products manufactured or sold under others' labels? YES NO

If YES, please also complete the attached CONTRACTOR MANUFACTURERS' LIABILITY ADDENDUM.

C) 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			
Holistic Medicines			
Cosmetics			
Other (please attach list of products):			
TOTAL			

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D) Are you a (if more than 1 (one) applies, check all)?

Manufacturer

Distributor

Research & Development

Is Research and Development for others?

YES NO

If YES, please fully describe. _____

Does your Company manufacture, distribute or conduct research and development on brand name pharmaceuticals?

YES NO

If YES, indicate actual revenues and contact your insurance broker.

E) 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? _____

F) 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): _____

G) 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): _____

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? _____

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: _____

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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: _____

I) 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 |

J) 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
 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: _____ U.S.: _____ 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: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Regulatory consulting: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| In-house design and prototyping: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Engineering: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Product labeling: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Packaging validation: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Material supply and management: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Inventory management: | <input type="checkbox"/> | YES | <input type="checkbox"/> | NO |
| Warehousing: | <input type="checkbox"/> | YES | <input type="checkbox"/> | 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

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

C) 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:

- Date of claim
- Claimant's name
- Nature of claim
- Amount of indemnity payment and amount of defense costs
- 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: _____