



PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

THIS APPLICATION IS FOR A CLAIMS MADE POLICY

PLEASE ENSURE THAT THE FOLLOWING ARE PROVIDED WITH THE APPLICATION

- Company brochures (if different than product description on the website)
- Product catalogue
- Curriculum vitae of key personnel
- Copies of all applicable contracts (i.e. development agreements, service agreements, license agreements, etc.)

1. GENERAL INFORMATION

1. Name of Organization or Legal Entity (Company) including any subsidiaries:

_____ (please show complete name as you wish it to appear on the policy)

2. Address (Not P.O. Box):

Website: _____

3. Location of Research Facilities: _____

4. Branch Offices (if any): _____

5. Parent Company: _____

6. Limit of Liability requested: \$1,000,000 \$2,000,000 Other: \$ _____

2. COMPANY INFORMATION

7. Date established: _____

8. Fully describe your Company's operations: _____

9. 1) Do you retail any products directly to the public through your own retail outlet(s) or direct from your website?

YES NO

2) Do you sell any products via infomercials?

YES NO

3) Do you sell any products through any multi level marketing channels?

YES NO

(If YES, please do not complete the remainder of this application and contact your insurance broker.)

10. 1) Gross Revenues for the last twelve (12) months or last fiscal year (\$CDN):

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

_____ \$ _____

_____ \$ _____

_____ \$ _____

PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

2) Estimated Gross Revenues for the next twelve (12) months or next fiscal year (\$CDN):
 CANADA \$ _____ U.S. \$ _____ OTHER (please list countries): _____ \$ _____
 _____ \$ _____
 _____ \$ _____
 _____ \$ _____

11. 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 (direct to public)						
Research (for others):						
Other (please specify):						
TOTAL (total figures in D1) must equal totals figures in D 2))						

3. PRODUCT INFORMATION

12. 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.

13. Are any products manufactured or sold under others' labels? YES NO
 If YES, please also complete the attached CONTRACTOR MANUFACTURERS' LIABILITY ADDENDUM.

14. 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			

15. 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. _____
16. 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: _____

17. Is your Company being held harmless in those instances where the product sterilization has been subcontracted out? YES NO
If NO, why not? _____

18. 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): _____

19. 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

20. 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: _____
21. 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? _____
22. 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? _____
23. 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? _____
24. Does your Company follow Good Manufacturing Practices (GMP)? YES NO
Are you ISO registered? YES NO
If YES, what level? _____
25. 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? _____

PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

26. 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:

27. Does your Company have live viruses on its premises? YES NO

If YES, please identify the viruses and advise how they are contained:

28. 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:

29. 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 |

30. Does your Company keep laboratory animals on the premises? YES NO

If YES, please indicate type of animals, the 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 TRIAL ADDENDUM for each trial.

If NO, please proceed to Section 7 (PREVIOUS INSURANCE).

31. Has the proposed clinical trial(s) been approved by the appropriate government authority(ies)? YES NO

If NO, please provide details:

32. Are all trial participants required to sign an informed consent form? YES NO

If NO, please explain why not?

33. 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

34. Who will be the principal investigator(s) in the clinical trial(s)? _____

PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

35. 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:

36. 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:

37. 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 ADDENDUM

(Please complete a separate Addendum 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:

38. Please indicate the percentage (%) of products made to the specifications of others: _____ %

39. Please indicate the percentage (%) of products made to your Company’s own specifications: _____ %

40. Does your Company manufacture and/or assemble the final product(s)? YES NO
 If NO, please explain: _____

41. Does your Company require signed final acceptance from its customers? YES NO
 If NO, please explain: _____

42. 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 |
| End-user shipping: | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| Logistics management: | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| Sales and marketing: | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| Other (please specify): _____ | <input type="checkbox"/> YES <input type="checkbox"/> NO |

PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

43. 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

44. 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: _____

45. 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	OCCURRENCE OR CLAIMS MADE	RETRO DATE

46. 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

47. Has your Company, its partners, directors, officers or employees ever had a written demand or civil proceedings for compensatory damages made against them during the last five (5) years? 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

48. Is your Company, its partners, directors, officers or employees aware of any job disputes or fee disputes during the last ten (10) years? YES NO
 If YES, please describe in detail:

PHARMACEUTICAL AND BIOTECHNOLOGY LIABILITY INSURANCE APPLICATION

49. 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 proceeding 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 above, 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 Beazley Canada Limited, a customer provides Beazley 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 Beazley's related or affiliated companies and service providers.

Further information about Beazley'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.

SIGNED: _____
(Authorized Representative)

DATE: _____

NAME (Please Print): _____

TITLE/POSITION: _____