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NATURAL HEALTH PRODUCTS 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 as you wish it to appear on the policy)

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

_____

_____

Website: _____

3. Branch Offices (if any):

_____

_____

4. Parent Company: _____

5. Limit of Liability requested: ☐ $1,000,000 ☐ $2,000,000 ☐ Other : $ _____

2. COMPANY INFORMATION

6. Date established: _____

7. Are you a (if more than 1 (one) applies, check all): ☐ Manufacturer ☐ Distributor ☐ Research & Development

Please fully describe your Company's operations.

_____

8. 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.)

9. 1) In $CDN, what are your gross revenues for the last twelve (12) months or your last fiscal year? (If using fiscal year, please specify your fiscal year-end).

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

_____ $ _____

_____ $ _____

_____ $ _____

2) In $CDN, what are 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. $_____ OTHER (please list countries): _____ $_____

_____ $_____

_____ $_____

_____ $_____

3. PRODUCT INFORMATION

10. 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.

11. 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?

_____

_____ _____

_____

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

13. 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, Diethylistbestrol, 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? ☐YES ☐NO
If YES, please explain.

_____

_____

14. 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.

15. Are any products manufactured or sold under labels of others? ☐YES ☐NO
If YES, please complete Section 6 (Contract Manufacturing).

16. 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	$	$	$

17. 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:

18. 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:

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

20. 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):

21. 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):

22. 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

23. 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: _____

24. 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? _____

25. 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? _____

26. 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? _____

27. Does your Company follow Good Manufacturing Practices (GMP)? ☐ YES ☐ NO
Are you ISO registered? ☐ YES ☐ NO
If YES, what level? _____

28. 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? _____

29. 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:
_____
_____

30. Does your Company have live viruses on its premises? ☐ YES ☐ NO
If YES, please identify the viruses and advise how they are contained:
_____
_____

31. 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:
_____
_____

32. Does your Company consult with legal counsel for issues concerning the following:

Contractual Liability	☐ YES	☐ NO	☐ Not Applicable
Product Labeling	☐ YES	☐ NO	☐ Not Applicable
Package Inserts	☐ YES	☐ NO	☐ Not Applicable
Product Guarantees	☐ YES	☐ NO	☐ Not Applicable
Promotional Materials	☐ YES	☐ NO	☐ Not Applicable
Instruction Manuals	☐ YES	☐ NO	☐ Not Applicable

33. 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.

34. 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).

35. Has the proposed clinical trial(s) been approved by the appropriate government authority(ies)? ☐YES ☐NO
If NO, please provide details:

36. Are all trial participants required to sign an informed consent form? ☐YES ☐NO
If NO, please explain why not?

37. 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:

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

39. 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:

40. 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:

41. 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:

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

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

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

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

46. 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
End-user shipping:	☐ YES ☐ NO
Logistics management:	☐ YES ☐ NO
Sales and marketing:	☐ YES ☐ NO
Other (please specify): _____	

47. 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)		

With Products Manufactured on behalf of a Third Party, does the Third Party company provide the following?

Product Labels(s): ☐ YES ☐ NO
Product Packaging: ☐ YES ☐ NO
Product Instruction Manuals: ☐ YES ☐ NO
Product Promotional Materials: ☐ YES ☐ NO
Product Warranty: ☐ YES ☐ NO
Packaging Training (if applicable): ☐ YES ☐ NO
Products Maintenance/Repair: ☐ YES ☐ NO

7. PREVIOUS INSURANCE

48. 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: _____

49. 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

50. 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

51. 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

52. 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:

_____

_____

_____

53. 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 this section, 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: _____ **DATE:** _____
(Authorized Representative)

NAME (Please Print): _____ **TITLE/POSITION:** _____