ADMIRAL INSURANCE COMPANY A Berkley Company®

DIETARY SUPPLEMENTS APPLICATION

I. GENERAL LIABILITY AND PRODUCT LIABILITY
II. TECHNOLOGY SECURITY & PRIVACY COVERAGE

INTRODUCTION

Admiral believes that the information collected with the completion and submission to us of this DIETARY SUPPLEMENTS APPLICATION will benefit the Nutraceutical / Dietary Supplement applicant/insured with the best possible pricing and coverage terms.
Admiral will accept other insurer's completed supplemental applications for Nutraceutical / Dietary Supplement businesses. Admiral's proposal, pricing, and final coverage, however, will be shaped by the type and quality of the information received.
Admiral Technology Security and Data Privacy coverage has been custom-designed for Nutraceutical / Dietary Supplement businesses. This coverage is only available by endorsement to the Admiral Nutraceutical / Dietary Supplement General Liability and Product Liability policy. Part II of this application may be used as a "standalone" questionnaire along with an acceptable Nutraceutical / Dietary Supplement General Liability and Product Liability supplemental application from another insurer. This coverage is not available without completion of the Part II.TECHNOLOGY SECURITY & PRIVACY COVERAGE portion of this application.

Check below to receive quotations for available coverage options:

☐ Technology Security and Privacy Coverage - Complete Part **II. TECHNOLOGY SECURITY AND PRIVACY COVERAGE** of this application

☐ Serious Adverse Event Coverage - Scheduled Events - Coverage available for future events. Provide past details as requested in Question 31

☐ Additional Insured - Vendors

☐ Limited Product Withdrawal Expense Coverage

☐ Limited Government-Ordered Product Withdrawal Expense Coverage
Completed Product Withdrawal Application

Certain terms are abbreviated in this application. Here are some:

DSHEA means the Dietary Supplement Health and Education Act of 1994 and amendments thereto.
FDA means the United States Food and Drug Administration.
FTC means the United States Federal Trade Commission.
QAP / QCP means Quality Assurance Program / Quality Control Program
cGMP / GMP means current Good Manufacturing Practices / Good Manufacturing Practices

For detailed information on regulatory requirements and definitions, you may find useful references at www.fda.gov and www.ftc.gov .

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Applicant Name:

Mailing Address:

Location Address:

Website

Agent's Name

Mailing Address:

Proposed Effective Date:

From:

To:

12:01 A.M, Standard Time at the address of the Applicant

I. GENERAL LIABILITY AND PRODUCT LIABILITY APPLICATION

Applicant is: ◯ Individual ◯ Joint Venture ◯ LLC ◯ Corporation ◯ Partnership ◯ Other - Specify

1) Years in Business under current and prior names:

2) Description of operations (check all that apply)

☐ Manufacturer - Finished Products Sold Under your Label
☐ Manufacturer - Ingredients Sold to Others - No Finished Products
☐ Wholesaler/Distributor - No Directly Imported Products
☐ Direct Importer
☐ Contract Manufacturer - Products Sold Under Label of Others
☐ Contract - Packager - For Others
☐ Other (Please Describe)

3) Are you a member of the Natural Products Association (NPA) or NSF International (NSF)? ◯ YES ◯ NO

4) Description of any product you make or sell that is not a dietary supplement as defined under the DSHEA or by the FDA:

5) Description of all acquisitions of companies and operations in the past 5 years:

6) Have you discontinued any product in the past five years for safety reasons? ◯YES ◯NO

If yes, please provide details:

7) Annual gross sales

	USA	Foreign
Upcoming Year (Estimate)	$	$
Prior Year (Actual)	$	$

Note: Insurance issued based on this application will not cover products containing Anabolic-Androgenic Steroids, Anabolic Steroids, Androstenedione, DHEA (Dehydroepiandrosterone), DMAA (Dimethylamylamine), Ephedra, Ephedrine Alkaloids (including but not limited to Cathine, Country Mallow, Epitonin, Herbal Phen Fen, Ma Huang, Norephedrine, Norpseudoephedrine, Phenylpropanolamine and Pseudoephedrine) or Fenfluramine (N-Nitroso-Fenfluramine).

**** GROSS SALES FOR ALL SUCH PRODUCTS SHOULD BE OMITTED FROM THIS APPLICATION. ****

8) Percentage of total gross sales generated by the following products (check each type product sold):

Upcoming Year (Estimate) % Prior Year (Actual) %

☐ For use by children ☐ Advertising weight loss benefits ☐ For bodybuilding

☐ Intended to treat erectile dysfunction/sexual impotence

For each type of product checked, please provide details:

9) Percentage of total gross sales generated by products containing one or more of the following ingredients (check all that apply):

Upcoming Year (Estimate) % Prior Year (Actual) %

- ☐ 1, 4 Butanediol (Gamma-Hydroxybutyric Acid)
- ☐ Aconite
- ☐ Aristolochic Acid
- ☐ Bitter Orange
- ☐ Bovine Organ/Glandular Extracts
- ☐ Chaparral
- ☐ Colloidal Silver
- ☐ Coltsfoot
- ☐ Comfrey
- ☐ Creatine
- ☐ Deer Velvet
- ☐ Germander
- ☐ Germanium
- ☐ Greater Celandine
- ☐ HCG(Human Chorionic Gonadotropin)
- ☐ Horsetail
- ☐ Jin Bu Huan
- ☐ Kava
- ☐ Lobelia
- ☐ L-Tryptophan
- ☐ Melamine
- ☐ Pennyroyal Oil
- ☐ St Johns Wort
- ☐ Yohimbe

Note: Legible copies of labels for products containing any of these ingredients must be attached to this application.

10) Percentage of your gross sales generated by the following types of operations:

a. Manufacturer - Finished Products Sold Under Your Label ____ %

b. Manufacturer - Ingredients Sold to Others - No Finished Products ____ %

c. Wholesaler/Distributor - No Directly Imported Products ____ %

d. Direct Importer ____ %

e. Contract-Manufacturer - Products Sold Under Label of Others ____ %

f. Contract-Packager - For Others ____ %

11) If you are a Manufacturer - Finished Products Sold Under Your Label or if you are a Manufacturer - Ingredients Sold to Others - No Finished Products

a. Are you fully compliant with FDA Current Good Manufacturing Practices (cGMP)? ◯YES ◯NO

b. Is your cGMP program certified by NPA or NTF? ◯YES ◯NO

c. Have you attained ISO 9000, QS 9000 or similar Certification? ◯YES ◯NO

d. Have you or will you use ingredients imported from foreign suppliers? ◯YES ◯NO

If yes, please attach a description of your Quality Assurance Program.

e. Do you contract the manufacturing of your product to others? ◯YES ◯NO

If yes, please provide the manufacturer's name and physical address, and attach a copy of the contract to this application:

12) If you are a Wholesaler/Distributor - No Directly Imported Products:

a. Please list the manufacturers and their physical addresses:

b. Percentage of your gross sales that come from suppliers who provide you with a certificate of insurance: ____ %

c. Percentage of suppliers who also provide you with additional insured-vendors coverage: ____ %

13) If you are a Direct Importer of finished products from companies located in countries other than the United States:

a. Please list the manufacturers and their physical addresses:

b. Are any foreign manufacturers or suppliers affiliated with you? ◯YES ◯NO

c. Do you take physical possession of the products you sell? ◯YES ◯NO

14) If you are a Contract-Manufacturer - Products Sold Under Label of Others:

a. What is the percentage of such products that are formulated entirely by that customer: ____ %

b. Percentage of your overall sales that consist of products sold under the labels of your customers: ____ %

c. Do you have a written contract with each customer that includes hold harmless and indemnification agreements in your favor? ◯YES ◯NO

15) If you are a Contract-Packager - For Others

a. Do you have a written contract with each customer that includes hold harmless and indemnification agreements in your favor? ◯YES ◯NO

16) Percentage of your gross sales generated by sales to:

a. Manufacturers of supplements in which your product is an ingredient only: ____ %

b. Wholesale distributors or retailers: ____ %

c. Direct to customers via retail stores operated by you ____ %

d. Direct to customers via internet ____ %

e. Others (please describe) _____ ____ %

17) Percentage of your advertising expenditures allocated to:

a. Television ____ %

b. Print Media ____ %

c. Internet (Other Than Your Website) ____ %

d. Others (please describe) _____ ____ %

18) Advertising

a. Is your advertising fully compliant with all applicable FDA and FTC regulations? ◯YES ◯NO

b. Has outside legal counsel reviewed your advertising and confirmed it is in compliance with FDA and FTC regulations? ◯YES ◯NO

c. Has the FDA or FTC ever reviewed your advertising? ◯YES ◯NO

d. Has your advertising ever been found to be non-compliant with FDA or FTC regulations? ◯YES ◯NO

19) Quality Assurance Program (QAP):

a. Do you maintain formal written quality control and testing procedures? ◯YES ◯NO

b. Is there a full time employee in charge of the QAP? ◯YES ◯NO

c. Are designs and formulas reviewed, tested and verified by others? ◯YES ◯NO

d. Testing:

i. Do you have pre-production testing of raw materials? ◯YES ◯NO

II. Percentage of each batch of finished product that is tested by you, regardless of who makes the product: ____ %

iii. Percentage of each batch of finished product tested by an independent testing facility, regardless of who makes the product: ____ %

e. Record Maintenance:

i. Do you maintain records of when and where your product was manufactured? ◯YES ◯NO

II. Do your records show to whom your product was sold and the date of sale? ◯YES ◯NO

iii. Can you identify the names of your ingredient and component material suppliers? ◯YES ◯NO

iv. Do you keep records of changes in formulas and advertising materials? ◯YES ◯NO

v. Do your records show a specific identification number for each package sold? ◯YES ◯NO

vi. How long do you keep records of tests, sales, advertising materials and instructions? _____

20) Can you identify your products from those of others? ◯YES ◯NO

21) Do you have a formal written product recall procedure? ◯YES ◯NO

22) Have you voluntarily or involuntarily recalled or withdrawn, or are you considering recalling or withdrawing, any products for any reason? ◯YES ◯NO

If yes, please attach all relevant documents for each recall and withdrawal.

23) Do any of your products include a New Dietary Ingredient as defined by the FDA? ◯YES ◯NO

If yes, please describe each ingredient and advise if you are in compliance with FDA regulations governing premarket notification and use of all such "new dietary ingredients"

24) Labels

a. Are your labels fully compliant with all applicable FDA and FTC regulations? ◯YES ◯NO

b. Has outside legal counsel reviewed your labeling and confirmed it is in compliance with the rules and regulations established by the FDA and FTC? ◯YES ◯NO

c. Has the FDA or FTC ever reviewed any of your labels? ◯YES ◯NO

d. Have your labels ever been found to be non-compliant with FDA or FTC regulations? ◯YES ◯NO

e. Do any of your labels make health claims for specific diseases or health-related conditions? ◯YES ◯NO

f. Do all of your labels include a disclaimer that the FDA has not evaluated the claims on your labels and that your products are not intended to diagnose, treat, cure or prevent any disease? ◯YES ◯NO

g. Do all of your labels include specific dosage directions and warnings? ◯YES ◯NO

Note: A legible copy of a label from at least one product must be attached to this application.

25) Are all facilities used to manufacture, process, pack or store your products registered with the FDA? ◯YES ◯NO

26) Describe any ongoing or planned clinical trials, including number of participants and who will conduct the trials:

27) **Attach your five year carrier and loss history**

Check here if no insured or uninsured losses in five years ☐

28) Are you aware of any incident, condition, circumstance, defect or suspected defect in any product or work, which may result in a claim or claims against you that are not listed above? ◯YES ◯NO If yes, please explanation below

29) Are you aware of any complaint or notice filed in the last three years with any governmental agency or industry regulatory body, including but not limited to the FDA or FTC concerning your product? ◯YES ◯NO If yes, please explanation below.

30) Are you aware of any study, analysis or trial conducted or being conducted by or on behalf of any governmental agency or industry regulatory body to examine the safety of your product? ◯YES ◯NO If yes, please explanation below.

31) In the past five years, have you submitted a Serious Adverse Event (SAE) Report to the FDA or has the FDA notified you of a Serious Adverse Event Report submitted directly by a health care provider, firm or consumer? ◯YES ◯NO
If yes, please attach a comprehensive list of all SAE's, along with copies of all reports and relevant documents.

32) In the past five years, has the FDA issued a Warning Letter or a Form FDA 483 to you for any reason? ◯YES ◯NO
If yes, please attach copies of each Warning Letter, Form FDA 483 and all relevant documents.

33) In the past five years, have you received an advisory letter or other notice of violation from the FTC? ◯YES ◯NO

34) Current Carrier:

Coverage Form: ☐ Occurrence ☐ Claims Made Retro Date

Limits: Deductible/SIR:

Premium: Rate:

Is current carrier offering renewal? ◯YES ◯NO

35) Desired Limits Deductible/SIR:

☐ I/We declare that I/we have reviewed this Application for accuracy before signing it, that the above statements and representations are true and correct, and that no facts have been suppressed or misstated. I/We understand that this is an application for insurance only and that the completion and submission of this Application does not bind the Company to sell nor the applicant to purchase this insurance. I/We nevertheless acknowledge that any contract of insurance issued by the Company in response to this Application will be in full reliance upon the statements and representations made in this Application.

Any person who knowingly and with intent to defraud any insurance company or other person, files an application for insurance, or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any material fact, commits a fraudulent insurance act, which is a crime and may also be subject to civil penalty.

I/We hereby declare that the above statements and particulars are true and I/we agree that this Application shall be the basis for any contract of insurance issued by the Company in response to it.

Electronic Signature of Applicant or Authorized Representative: _____ Current Date: _____

Title _____

If you prefer not to return application with an electronic signature, please print and sign below:

Signature of Applicant or Authorized Representative _____ Current Date: _____

Title _____

See next page for part **II. TECHNOLOGY SECURITY AND PRIVACY COVERAGE APPLICATION**

The TECHNOLOGY SECURITY AND PRIVACY COVERAGE ENDORSEMENT is Available Only As An Enhancement To The CGL Policy. It Is Not Available for Products-Only Policies.

II. TECHNOLOGY SECURITY & PRIVACY COVERAGE APPLICATION

Answers to the following questions are required for a quotation to include Technology Security and Privacy Coverage:

1) Do you have a formal, documented data security policy? ◯YES ◯NO
   Are all employees required to read, receive and understand the security policy? ◯YES ◯NO

2) Do you utilize encryption for data stored? ◯YES ◯NO
   Do you utilize encryption for data transmitted between locations or systems? ◯YES ◯NO

3) Do you have the ability to remotely access and monitor mobile hardware? ◯YES ◯NO

4) Do you backup computer systems and data? ◯YES ◯NO
   If yes, how often are backups performed?
   Are backups stored off site? ◯YES ◯NO

5) Are your computer systems and networks actively monitored? ◯YES ◯NO
   If yes, by whom?
   If yes, how frequently?

6) Please describe your IT employee hiring and screening procedures:

7) Have you experienced any security breaches or data loss events? ◯YES ◯NO
   If yes, please explain the specifics and any action taken to prevent additional breaches or events:

☐ I/We declare that I/we have reviewed this Application for accuracy before signing it, that the above statements and representations are true and correct, and that no facts have been suppressed or misstated. I/We understand that this is an application for insurance only and that the completion and submission of this Application does not bind the Company to sell nor the applicant to purchase this insurance. I/We nevertheless acknowledge that any contract of insurance issued by the Company in response to this Application will be in full reliance upon the statements and representations made in this Application.

Any person who knowingly and with intent to defraud any insurance company or other person, files an application for insurance, or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any material fact, commits a fraudulent insurance act, which is a crime and may also be subject to civil penalty.

I/We hereby declare that the above statements and particulars are true and I/we agree that this Application shall be the basis for any contract of insurance issued by the Company in response to it.

Electronic Signature of Applicant or Authorized Representative:

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Title

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