ADMIRAL INSURANCE COMPANY a W. R. Berkley Company

HEALTH, NUTRITION & LIFESTYLE APPLICATION

I. GENERAL LIABILITY AND PRODUCT LIABILITY

Applicant Name:

Mailing Address:

City: State: Zip Code:

Location Address:

City: State: Zip Code:

Website: Proposed Effective Date:

From: To:

*12:01 AM Standard Time at the address of the Applicant

GENERAL LIABILITY AND PRODUCT LIABILITY

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

1) Years in Business under Current and Prior Names
(Please list all acquisitions of companies and operations in the past 5 years):

YOUR OPERATIONS

2) Description of Operations/List Products and Goods:

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

a. Manufacturer OR ____ %

b. Contract-Manufacturer ____ %

c. Wholesaler/Distributor - products of others sold under label of others ____ %

d. Importer - (Any products shipped directly to your customers without physical possession will not be considered as an acceptable form of business.) ____ %

e. Retailer - own label ____ %

f. Retailer - products of others sold under label of others ____ %

g. Direct to customers via internet ____ %

h. Other (please describe): ____ %

YOUR PRODUCT SALES

Annual Sales:	Year to Year	United States	Foreign
Upcoming Year			
Current Year			
First Prior Year			
Second Prior Year			
Third Prior Year			

Percentage of total Gross Sales generated by the following types of products (if none, enter 0):

	Upcoming Policy Year (Estimate):	Prior Policy Year (Actual):
a. For use by children	%	%
b. Caffeine exceeding 300 mg per serving (all sources)	%	%
c. Animal & vet supplements	%	%
d. Sports nutrition – bodybuilding, muscle enhancement	%	%
e. Weight Loss supplements	%	%
f. Sexual Enhancement supplements	%	%
g. Cannabinols (CBD)/Hemp products	%	%

NOTE: Coverage will not apply to products containing ingredients banned by the FDA, including but not limited to Steroids, including any product, supplement, additive, substance, ingredient or compound controlled or banned by the Anabolic Steroid Control Act of 1990 including amendments thereto, or the Anabolic Steroid Control Act of 2005; DMAA (Dimethylamylamine) (1,3 - Dimethylamylamine); Ephedra; Ephedrine Alkaloids; or Fenfluramine (N-Nitroso-Fenfluramine).

4) If you are a Manufacturer, Contract Manufacturer, Distributor or Retailer – Finished Products Sold Under Your Label:

a. Have you or will you use ingredients imported from foreign suppliers? ☐ Yes ☐ No

b. Do you contract the manufacturing of your product to others? ☐ Yes ☐ No

If yes, please provide the manufacturer's name and physical address:

5) If you are a Wholesaler/Distributor – Products of Others Sold Under Labels of Others:

a. Please list the manufacturers and their physical addresses:

b. Do your suppliers each provide you with a certificate of liability insurance? ☐ Yes ☐ No

c. Do your suppliers also each provide you with additional insured-vendors coverage? ☐ Yes ☐ No

6) If you are an Importer, please list the countries of origin:

7) 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 the customer? ____ %

b. Percentage of 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

d. Do you exclusively use ingredients supplied by your customer? ☐ Yes ☐ No

8) 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

YOUR QUALITY CONTROL AND REGULATORY COMPLIANCE

9) Product Withdrawal/Product Recall:

a. Do you have a formal written product recall procedure? ☐ Yes ☐ No

b. 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 provide details:

10) Current Practices or your specified industry equivalent:

a. Are you fully compliant with FDA Current Good Manufacturing Practices (cGMP)? ☐ Yes ☐ No

b. Are you compliant with FDCA-21 CFR III Act? ☐ Yes ☐ No

11) Quality Assurance Program (QAP)/Quality Control Program (QCP):

a. Have you attained ISO 9000, QS 9000 or similar registration or third party certification? ☐ Yes ☐ No

b. Do you have a formal written QAP (or SOP) that is in full compliance with all applicable federal regulations and industry standards? ☐ Yes ☐ No

c. Please provide name, title and contact information (email/phone) for QAP/SOP Manager:

12) Are all facilities used to manufacture, process, pack, hold or store your products registered with the FDA? ☐ Yes ☐ No

13) If you are making or selling any Cannabinols/CBD products are they tested & certified by a 3rd party laboratory? ☐ Yes ☐ No

a. Do you have documentation for each batch/lot? ☐ Yes ☐ No

b. Are your products certified to contain no more than 0.3% THC and is it listed on the label? ☐ Yes ☐ No

c. Has FDA form 483 been responded to, w/FDA closeout letter? ☐ Yes ☐ No

14) Labels:

a. Has outside legal counsel reviewed your labeling and confirmed it is in compliance with the regulations established by the FDA and FTC? ☐ Yes ☐ No

b. 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

c. Are you making any structure/function claims to substantiate your product claims? ☐ Yes ☐ No

d. Have you or will you conduct human clinical trials to substantiate your product claims? ☐ Yes ☐ No

REGULATORY EVENTS

15) In the past five years, have you submitted a Serious Adverse Event Report (SAER) 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.

16) Do you have a QAP/SOP detailing how to identify and handle on SAER/SAE? ☐ Yes ☐ No

17) 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 provide a detailed explanation:

18) Have you been inspected by the FDA? ☐ Yes ☐ No

a. Did the FDA issue a 483 Notice of Inspection? ☐ Yes ☐ No
If yes please provide a copy with your response.

b. Are you aware of any study, analysis or trial conducted by the FDA, or any industry regulatory body, to examine the safety of your products? ☐ Yes ☐ No

19) Do you comply with Prop 65 labeling requirements? ☐ Yes ☐ No

OPTIONAL COVERAGE ENHANCEMENTS

20) Hired & Non-Owned Auto

a. Do you own any auto that is used in your business? ☐ Yes ☐ No

b. Will any vehicle be operated beyond a 50 mile radius of the business location Address? ☐ Yes ☐ No

c. Does the applicant have more than five (5) employees? ☐ Yes ☐ No

d. Will any vehicle be used for product delivery? ☐ Yes ☐ No

21) Employee Benefits ☐ Yes ☐ No
(Please provide expiring Declarations page or retro will be inception of the Admiral policy)

YOUR CLAIMS, LOSSES, DEMANDS FOR DAMAGES AND SIMILAR EXPERIENCE

☐ Check here if no insured losses in the last 5 years

22) Are you aware of any incident, condition, circumstance, lawsuit, legal action or suspected defect in any product or work, which may result in a demand for damages or claims against you that are not listed in the 5 year carrier loss history? ☐ Yes ☐ No

If yes, please provide a detailed explanation:

23) Current Carrier:

Is current carrier offering renewal? ☐ Yes ☐ No

Coverage Form: ☐ Occurrence ☐ Claims Made **If Claims Made, Retroactive Date:**

Limits: $ Deductible: $

Premium: $ Rate: $

24) Desired Limits: $ **Desired Deductible: $**

Please initial: _____ 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 and 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.

Please initial: _____ 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: _____

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

Title: _____

Certain terms are abbreviated in this application. Here are a few:

DSHEA means the Dietary Supplement Health and Education Act of 1994 and amendments thereto
FDA means the United States Food and Drug Administration
FDCA-21CFR Part 11 means Food Drug and Cosmetic Act
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
CBD/Cannabidiol is a psychoactive ingredient found in plant species cannabis sativa
Prop 65 refers to the Safe Drinking Water and Toxic Enforcement Act of 1986

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

Please provide any additional details in the space provided: