NUTRA RISK™
An Amwins Specialty

Morgan Moore III
Executive Vice President
morgan.moore@amwins.com
Direct: (213) 236-4566

Stacy Kent
Assistant Vice President
stacy.kent@amwins.com
Direct: (213) 236-4575

H&L / CBD APPLICATION

SECTION I – APPLICANT INFORMATION

Business Name & DBA:

Agent's Name:

Mailing Address:

Mailing Address:

Location Address:

Proposed Effective Date:
From: 12:01 A.M. Standard Time at the address of the Applicant
To:

Website:

Business Inception Date:

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

Are your operations performed at a residence? ◯ Yes ◯ No

SECTION II – YOUR PRODUCT SALES

1) Description of operations/list products and goods:

Confirm, does any applicant listed have any operations, websites and/or any receipts or income from any products, goods or services, NOT reflected on the applications submitted? ◯ Yes ◯ No

Has there been any change in products or operations in the last 12 months? ◯ Yes ◯ No

Annual Gross Sales:	Total	United States	Foreign
Upcoming Year			
Current Year			
Prior Year			

2) Percentage of total gross sales generated by the following types of products (if none, enter 0):

	Upcoming Year (Estimate):	Prior Year (Actual)
a. Caffeine exceeding 300 mg per serving (all sources)	%	%
b. Cannabidiol (CBD)/hemp products	%	%
c. Electronic cigarettes, vaping devices and related accessories including replacement batteries	%	%

3) If you have or will make or sell any of the following products, please check all that apply:

☐ Electronic Cigarettes ☐ Vaping Devices ☐ E-liquid ☐ CBD Vape Oil

☐ Replacement Batteries ☐ Battery Rechargers ☐ Blunts / Smokeable Hemp

SECTION III – YOUR OPERATIONS

4) Are you a franchise Location? ○ Yes ○ No

If yes, which are you? ☐ Franchisee ☐ Franchisor

Please provide a copy of the Franchise Agreement.

5) Any acquisitions of companies and operations in the past 5 years? ○ Yes ○ No
If yes, please list all.

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

a. Manufacturer ____ %

b. Contract-Manufacturer – Products made solely to the specification of others and sold under their labels ____ %

c. Contract Packaging / Labeling – Offer packaging and labeling services for third parties using customers' labels ____ %

d. Wholesale / White Labeling – Your products *sold in bulk* to third parties under their labels ____ %

e. Distributor – Products of others *sold on their behalf* ____ %

f. Importer (Note: Products shipped directly to your customers without physical Possession will not be considered as an acceptable form of business) ____ %

g. Retailer – Own label ____ %

h. Retailer – Products of others sold under label of others ____ %

i. Extractor ____ %

j. Grower ____ %

k. Other (please describe): ____ ____ %

7) If you are a **Manufacturer or Retailer** – Own 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:

8) If you are a **Wholesaler / White Labeler** – Your formulated and manufactured products sold in bulk under labels of others:

a. Are you cGMP compliant? ○ Yes ○ No

b. Do you provide a Certificate of Analysis to your customers upon delivery of the finished product? ○ Yes ○ No

c. Do you maintain batch records on file that document production details for each lot of finished product? ○ Yes ○ No

d. Do your customers each provide you with a certificate of liability insurance? ○ Yes ○ No

e. Do your customers each provide you with additional insured-vendors coverage? ○ Yes ○ No

9) If you are a **Contract-Manufacturer** – Products made solely to the specification of others and sold under their labels:

a. Are you offering ground-up / comprehensive customized formulation services for third parties? ○ Yes ○ No

b. Are you creating / designing original labels, warnings, instructions for use or any other regulatory required wording for others? ○ Yes ○ No

c. Is your team's combined years of experience in the contract manufacturing, formulating, and labeling field under 3 years? ○ Yes ○ No

IF FOR THE ABOVE THREE QUESTIONS, ANY ANSWERS ARE "YES", THIS RISK WILL NO LONGER QUALIFY FOR THE HNL PROGRAM.

d. What is the percentage of overall sales that consist of products sold under the labels of your customers? _____ %

e. Do you have a written contract with each customer that includes hold harmless and indemnification agreements in your favor? ○ Yes ○ No

f. Are you cGMP compliant? ○ Yes ○ No

g. Do your customers each provide you with a certificate of liability insurance? ○ Yes ○ No

h. Do your customers each provide you with additional insured-vendors coverage? ○ Yes ○ No

i. Are you manufacturing products other than the products outlined on the application? ○ Yes ○ No

j. Please provide a list of the products you will be manufacturing for others:

k. Do you confirm that your customers have their own Products Liability insurance and product recall procedures in place? ○ Yes ○ No

l. Do you purchase Professional E&O Coverage for possible financial inquiries due to errors and omissions on your part? ○ Yes ○ No

m. Are you designing labels, warnings, instructions for use or any other regulatory required wording for others? ○ Yes ○ No

n. Do you provide Certificates of Analysis to your customers upon delivery of the finished product? ○ Yes ○ No

o. Please confirm the number of customers for whom you provide contract manufacturing services:

10) If you are a **Contract-Packager / Labeler** – For Others:

a. Do you have a written contract with each customer that includes hold harmless and mutual indemnification wording favorable to you? Yes No

b. Are you responsible for developing warnings, instructions for use or any other regulatory required wording? Yes No

c. Do you purchase Professional E&O coverage for possible financial injuries due to errors and omissions on your part? Yes No

d. Please confirm the number of customers for whom you provide contract packaging and labeling services:

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

a. Are you importing any products? Yes No
If yes, can you confirm all products imported into the US are tested in the U.S. with proper quality assurance and quality controls and all products are all shipped from the U.S.? Yes No

12) Retailers: N/A Yes No

a. Name and address of manufacturers/suppliers:

b. Please list details on Quality Control/Quality Assurance in place:

c. Are manufacturers/suppliers cGMP compliant? Yes No

d. Are agreements in place? Yes No

e. Do your suppliers provide you with Certificates of Insurance? Yes No

If yes, are they named as an Additional Insured? Yes No

f. Are inventory records kept? Yes No

g. Are there recall procedures in place by you or the manufacturer? Yes No

13) Vape exposure (including CBD vape products): N/A Yes No

a. Name and address of manufacturer:

b. Sales breakout of each type of vape products:

Vape Devices %

Cartridges %

E-liquids %

Batteries %

Other: %

c. Are products UL8139 compliant? Yes No

d. Are E-liquids sold in childproof containers? Yes No

e. Are E-liquid products CBD only, confirmed to have no nicotine or tobacco? Yes No

f. Do battery chargers have auto safety cut-off to prevent overcharging? Yes No

g. Are there any replacement batteries? Yes No

If yes, are they equipped with a protection circuit to prevent thermal runaway? Yes No

14) Extraction/processing: N/A Yes No

a. Are you performing any extraction operations? Yes No

If no, please provide the name and address of the company extracting and skip to question 15:

If yes, please answer questions 14 b-m.

b. Will there be any residential operations? Yes No

c. What method of extraction will be used?

d. Is the equipment used for extraction certified commercial equipment that is certified and tested for its intended use? Yes No

e. Will the equipment be operated by certified technicians or engineers? Yes No
If no, who is operating and what experience do they have?

f. Will the hemp be tested for metals, pesticides, THC levels, and solvent residue? Yes No

g. What solvents will be used in the process?

h. Does the extraction facility comply with Class 1, Division 2 electrical requirements? Yes No

i. Are you in compliance with all regulations, laws and ordinances that involve the use, storage, handling and disposal of any gases used in the operations? Yes No

j. Is your extraction facility in compliance with State and local fire codes for this type of business? Yes No

k. Is the extraction done in a fireproof contained area? Yes No

l. Does the location where you are manufacturing require a business license? Yes No

If yes, have you obtained one? Yes No

m. Are you the sole occupant of the building? Yes No

15) Growers: N/A Yes No

a. Will operations include growing or cultivating:

Indoor Outdoor Greenhouse

b. Do you have a license to grow hemp? Yes No

c. Are you also selling any consumer products containing hemp or CBD? Yes No

d. Do you provide Certificate of Analysis to your customers to confirm product purity and the THC content? ◯ Yes ◯ No

e. Is THC content more than 0.3%? ◯ Yes ◯ No
If Yes, coverage will not be available.

f. Do your farming operations include extracting on site? ◯ Yes ◯ No

g. If applicable, please provide a complete Named Insured List:

SECTION IV – YOUR QUALITY CONTROL AND REGULATORY COMPLIANCE

16) Product Withdrawal/Product recall:

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

If you do not at this time, when do you plan to have one in place? Date:

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:

17) Current practices or your specified industry equivalent:

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

If you are not cGMP compliant at this time, when do you plan to have in place? Date:

b. Are you compliant with Food, Drug & Cosmetic Act 21 CFR 111? ◯ Yes ◯ No

c. Have you been Certified cGMP Compliant? ◯ Yes ◯ No
If yes, please list the Accredited Certifying Body along with the date of certification:

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

a. Have you attained an ISO 9000, QS 9000 or similar third party certification for your quality systems? ◯ Yes ◯ No

List any and all others:

b. Do you have a formal written Quality Assurance Program/Quality Control Program, including writing Standard Operating Procedures that control your operations? ◯ Yes ◯ No

c. Please provide name, title and contact information (email/phone) for Quality Assurance Program/Quality Control Program manager:

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

20) Are you making or selling any Cannabidiol (CBD) products? ◯ Yes ◯ No

a. Do you have batch records on file that document production details for each lot of finished products? ◯ Yes ◯ No

b. Are your products certified to contain no more than 0.3% THC? Yes No

Is it listed on the label? Yes No

c. Are your products tested and certified by a third party laboratory? Yes No

d. Do you obtain your hemp or CBD products from a licensed grower in the U.S.? Yes No

If no, to 20) d., coverage for CBD will not be available.

21) Labels:

a. Has 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 for your products on labels, websites or other marketing materials? Yes No

d. Do you maintain documentation that substantiates each claim you make? Yes No

e. Have you conducted or are you planning to conduct, human clinical trials to substantiate your product claims? Yes No

SECTION V – REGULATORY EVENTS

22) In the past five years, have you submitted a Serious Adverse Event Report (SAER) to the FDA or has the FDA notified you of an SAER submitted directly by a health care provider, firm or consumer? Yes No

If yes, please attach a comprehensive list of all Serious Adverse Events, along with copies of all reports and relevant documents.

23) Do you have an SOP detailing how to identify and handle an SAER/SAE? Yes No

24) 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 attach a detailed explanation.

25) Have you been inspected by the FDA? Yes No

a. Did the FDA issue a Form 483 notifying you of any objectionable conditions? Yes No

If yes, please provide a copy and your written response to the FDA.

b. Has FDA Form 483 been responded to with an FDA closeout letter? Yes No

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

If you do not comply, coverage will not be available.

SECTION VI – OPTIONAL COVERAGE ENHANCEMENTS

27) Hired & Non-Owned Auto

Please check all of the following that apply if you would like to be considered for Hired & Non-Owned Auto Liability (HNOA) coverage:

a. Do you have a separate Auto Liability policy? Yes No

b. Do you ***own*** any auto that is used in your business and is registered to your company? Yes No

c. Will you have more than five employees using their personal auto for business use/ ◯ Yes ◯ No

d. Will any vehicle be operated beyond a 50-mile radius of the business location address on a weekly basis? ◯ Yes ◯ No

e. Will any vehicle be used for product delivery? ◯ Yes ◯ No

If yes, *(to any of the above questions), HNOA coverage will not be available.*

SECTION VII – YOUR CLAIMS, LOSSES, DEMANDS FOR DAMAGES AND SIMILAR EXPERIENCES

Check here if no insured or uninsured losses in the past 5 years ☐

28) Are you aware of any investigation, incident, condition, circumstance, lawsuit, legal action or suspected defect in any product or work, which has resulted in or may result in demand for damages or claims against you that are not listed in the 5 years carrier loss history? ◯ Yes ◯ No

If yes, please attach a detailed explanation.

29) Current Carrier:

Is current carrier offering renewal? ◯ Yes ◯ No

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

Limits: $ Deductible: $

Premium: $ Rate: $

30) Desired Limits: $ Desired Deductible: $

For detailed information on regulatory requirements and definitions, you may find useful references at:

www.fda.gov and www.ftc.gov

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); Kratom; or Phenibut.

RESET SAVE PRINT EMAIL

Applicable in AL, AR, DC, LA, MD, NM, RI and WV: Any person who knowingly (or willfully)* presents a false or fraudulent claim for payment of a loss or benefit or knowingly (or willfully)* presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison. *Applies in MD only.

Applicable in CO: It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

Applicable in FL and OK: Any person who knowingly and with intent to injure, defraud or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony (of the third degree)*. * Applies in FL only.

Applicable in KS: Any person who knowingly and with intent to defraud, presents, causes to be presented, or prepares with knowledge or belief that it will be presented, to or by an insurer, purported insurer, broker or any agent thereof, any written statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

Applicable in KY, NY, OH and PA: 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 fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties (not to exceed five thousand dollars and the stated value of the claim for each such violation)*. *Applies in NY only.

Applicable in ME, TN, VA, and WA: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties (may)* include imprisonment, fines and denial of insurance benefits. *Applies in ME only.

Applicable in NJ: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

Applicable in OR: Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

Applicable in PR: Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

Applicable in all other States: 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 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 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:

Title: Date:

If you prefer not to return the questionnaire with an electronic signature, please print and sign.