



HEALTH, NUTRITION & LIFESTYLE APPLICATION

Business Name (including all DBAs):

Mailing Address:

Location Address:

Website Address(es):

Business Inception Date:

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

SUBMISSION REQUIREMENTS

- 5 years of currently valued carrier issued Loss Runs

SECTION I – RISK PROFILE

- | | | |
|--|-----|----|
| 1) If the Applicant is a Grower of Hemp or Cannabidiol (CBD), is Delta-9 THC content more than 0.3% ? | Yes | No |
| (Note: If answered “Yes” to this question, this risk will be deemed ineligible and declined coverage.) | | |
| 2) Please provide the percentage of gross sales generated as an Importer – Directly Importing Ingredients or Finished Products. | | % |
| (Note: Applicants that have products drop shipped directly to customers without physical possession this risk will be deemed ineligible and declined coverage.) | | |
| 3) Does the Applicant comply with the following requirements/industry standards: | | |
| a. Prop 65 labeling requirements? | Yes | No |
| (Note: If the answer to the above question is “No”, coverage will be deemed ineligible.) | | |
| b. cGMP? | Yes | No |
| c. Food, Drug, & Cosmetic Act 21 CFR 111? | Yes | No |
| 4) Bankruptcy - Within the last 5 years, were there any pending or planned bankruptcies, or judgements for unpaid taxes against the Applicant, or a majority partner? | Yes | No |
| 5) Are the Applicant’s operations performed at a residence? | Yes | No |

- 6) Is Applicant controlled by, owned by, or commonly owned, affiliated or associated with any other organization? Yes No
 If Yes, confirm the legal entity name and operations of each, including organizational structure with ownership details:

SECTION II – ESTIMATED EXPOSURES

- 7) Please confirm total sales of products, goods and services:

Annual Gross Sales:	Total	United States	Foreign
Next 12 Months			
Current Year			
Prior Year			

- 8) Please provide a description of operations, list all products and goods, and advise if there have been any changes in products, goods, or operations within the last 12 months:

- 9) Please provide the 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. Hemp/CBD vaping devices and related accessories including cartridges & disposables	%	%
d. Class I & Class II Medical Products / Devices	%	%

- 10) Please check all of the following products that the Applicant **will** make or sell, or **has** been made or sold in the past:

Nicotine / Tobacco Electronic Cigarettes	Hemp Vaping Devices	Cartridges/E-liquid
CBD Vape Oil	Replacement Batteries	Battery Rechargers
Blunts / Smokable Hemp		

SECTION III – YOUR OPERATIONS

(In this section, please check N/A if the Applicant does not perform the operations and the question doesn't apply. Do not complete questions in any section that is marked N/A and does not apply to your operation.)

- 11) Any acquisitions of companies and operations in the past 5 years? Yes No N/A
 If Yes, please list all:

12) Any Research and Development? If Yes, please provide details:	Yes	No	N/A
13) Please provide the percentage of gross sales generated by the following types of operations:			
a. Manufacturer – Applicant’s Proprietary product formula that the Applicant manufactures in the Applicant’s facility			%
b. Contract Manufacturer – Products that are custom developed and formulated for third parties and sold under third party labels			%
c. Contract Manufacturer – Products made based on the Applicant’s proprietary formula, or solely to the specification of the third-party customer formula and sold under third party customer labels (no custom formulation)			%
d. Contract Packaging – Packaging services to third parties using third party labels (no labeling services)			%
e. Contract Labeling – Offering custom labeling services to third parties and sold under third party labels			%
f. Wholesale / White Label – Applicant proprietary formulated and manufactured products sold in bulk under labels of others			%
g. Distributor – Products of others sold under labels of others on behalf of others			%
h. Retailer (Own Label) – Products sold under the Applicant’s own label or brand			%
i. Retailer – Products of others sold under label of others			%
j. Extractor – Hemp or other			%
k. Grower - Hemp			%
l. Other (please describe):			%
14) If the Applicant is a Manufacturer or Retailer – (Own Label), please confirm if the Applicant:			N/A
a. Has or will use ingredients imported from foreign suppliers? If Yes, list the Countries of Origin:		Yes	No
b. Contracts the manufacturing of their product to others? If Yes, please provide the manufacturer’s name and physical address:		Yes	No
15) If the Applicant is a Wholesaler / White Labeler – (Applicant proprietary formulated and manufactured products sold in bulk under labels of others), please confirm if the Applicant:			N/A
a. Provides a Certificate of Analysis to customers upon delivery of the finished product?		Yes	No
b. Maintains batch records on file that document production details for each lot of finished product?		Yes	No
c. Confirms that customers carry their own liability coverage and obtain a Certificate of Liability Insurance?		Yes	No
16) If the Applicant is a Contract-Manufacturer – (Products that are custom developed and formulated for third parties and sold under third party labels / Products made based on Applicant’s proprietary formula, or solely to the specification of the third-party customer formula and sold under third party customer labels), please confirm if the Applicant:			N/A

a.	Is offering any product development or custom formulation services to third party customers? If Yes, confirm the credentials and experience of individuals signing off on formulation specifications:	Yes	No
b.	Is creating / designing original labels, warnings, instructions for use or another other regulatory required wording for others? If Yes, confirm the credentials and experience of individuals signing off on label specifications, including name of the law firm if one is used:	Yes	No
c.	Team has a minimum of three years of experience in the contract manufacturing, formulating, and labeling field?	Yes	No
d.	What percentage of total sales are from products sold under labels of others?		%
e.	Has written contracts or manufacturing agreements in place with clients? If Yes, do they contain mutual indemnification wording?	Yes	No
f.	Confirms that customers carry their own Product Liability coverage for products sold under their own label?	Yes	No
g.	Confirms that customers have formal, written product recall procedures in place?	Yes	No
h.	Provides Certificates of Analysis to customers upon delivery of the finished product?	Yes	No
i.	Please confirm the number of customers for whom the Applicant provides contract manufacturing services:		
17)	If the Applicant is a Contract Packager / Contract Labeler – please confirm if the Applicant:		N/A
a.	Has a written contract with each customer that includes hold harmless and indemnification agreements in the Applicant’s favor?	Yes	No
b.	Is responsible for developing warnings, instructions for use, or any other regulatory required wording?	Yes	No
c.	Please provide the total number of customers for whom the Applicant provides contract packaging and labeling services:		
18)	If the Applicant is an Importer , please confirm the following:		N/A
a.	Please list the countries of origin:		
b.	Are all imported products and/or ingredients tested in the U.S. with proper quality assurance and quality controls?	Yes	No
c.	Does the Applicant take physical possession of all products and/or ingredients directly imported to them?	Yes	No
19)	If the Applicant is a Retailer , please provide the following information:		N/A
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. Are suppliers Certificates of Insurance obtained? | Yes | No |
| If Yes, is the Applicant named as an Additional Insured? | Yes | No |
| f. Are inventory records kept? | Yes | No |
| g. Are there recall procedures in place by the Applicant or the manufacturer? | Yes | No |

20) **Vape exposure** (including CBD vape products), please provide the following information: N/A

- | | | |
|--|-----|----|
| a. Name and address of manufacturer: | | |
| b. Is the Applicant aware of the PACT ACT for Vape Products? | Yes | No |
| Does the Applicant comply with the PACT ACT? | Yes | No |
| c. Please provide the gross sales of each of the following types of vape products: | | |
| Vape Devices /Disposables | \$ | |
| Cartridges | \$ | |
| E-liquids | \$ | |
| Batteries | \$ | |
| Other: | \$ | |
| d. Are products UL8139 compliant? | Yes | No |
| e. Are E-liquids sold in childproof containers? | Yes | No |
| f. Are products Hemp only, confirmed to have Nicotine or Tobacco? | Yes | No |
| g. Do battery chargers have auto safety cut-off to prevent overcharging? | Yes | No |
| h. Are there any replacement batteries? | Yes | No |
| If Yes, are they equipped with a protection circuit to prevent thermal runaway? | Yes | No |

21) If the Applicant is performing **extraction/processing**, please answer the following questions: N/A

- | | | |
|--|-----|----|
| a. Does the Applicant perform any extraction operations? | Yes | No |
| If No, please provide the name and address of the company extracting and skip to question 22: | | |
| If Yes, please answer questions 21) b.- h. | | |
| b. Will there be any residential operations? | Yes | No |
| c. What method of extraction will be used? | | |
| d. Is the equipment commercial grade, certified and tested for its intended use, and operated by certified technicians or engineers? | Yes | No |
| If No, who is operating and what experience do they have? | | |
| d. Will the hemp be tested for metals, pesticides, THC levels, and solvent residue? | Yes | No |
| e. What solvents will be used in the process? | | |

- | | | | |
|-----|--|-----|-----|
| f. | Does the extraction facility comply with Class 1, Division 2 electrical requirements, state and local fire codes, and all regulations, laws and ordinances that involve the use, storage, handling and disposal of any gases used in the operations? | Yes | No |
| g. | Is the extraction done in a fireproof contained area? | Yes | No |
| h. | Is the Applicant the sole occupant of the building? | Yes | No |
| 22) | If the Applicant is a Grower , please answer the following questions: | | N/A |
| a. | Will operations include growing or cultivating in any of the following? (Check all that apply.) | | |
| | Indoor Outdoor Greenhouse | | |
| b. | Does the Applicant have a license to grow hemp? | Yes | No |
| c. | Are consumer products containing CBD being sold? | Yes | No |
| d. | Are customers provided with Certificates of Analysis to confirm product purity and the THC content? | Yes | No |
| e. | Do farming operations include extraction on site? | Yes | No |
| 23) | If the Applicant manufactures or sells Class I & Class II Medical Products / Devices , please confirm the following questions: | | N/A |
| a. | Is the device used as a component part of someone else's end product / device?
If Yes, please list products you manufacture that are a component of others end products / device: | Yes | No |
| b. | Any past or present association with any of the products listed: <i>Latex Gloves, Breast Implants, Hip, Knee, Spinal Devices or Implants, DEHP, Pedicle Screws, IUD Devices Animal / Human Derived Products?</i> | Yes | No |
| c. | Does the Applicant hire licensed medical professionals to sell, design or offer instruction related to the use of the products? | Yes | No |
| d. | Does the Applicant repair, install, or service any products? | Yes | No |
| e. | Are Material Data Safety Sheets and Scheduled Maintenance Procedures issued to each customer? | Yes | No |

SECTION IV – HEMP & CANNABIDOL (CBD)

- | | | | |
|-----|---|-----|----|
| 24) | Does the Applicant manufacture or sell any Hemp/Cannabidiol (CBD) products?
If No, please provide the name and address of the CBD Manufacturer and supplier: | Yes | No |
| a. | Are batch records documenting the production details for each lot of finished products kept on file? | Yes | No |
| b. | If the products are certified to contain no more than 0.3% Delta-9 THC , is that certification listed on the label, and has the product been tested and certified by a third-party laboratory? | Yes | No |
| c. | Are hemp or CBD products sourced from a licensed grower in the U.S.?
(Note: If answered "No", to 24) a-c., coverage for CBD will be unavailable.) | Yes | No |
| 25) | Are all of the cannabinoids contained in the products extracted from legally cultivated hemp? | Yes | No |

26) Are all of the CBD and other cannabinoid products being sold where regulated, tested, and labeled CBD/cannabinoid products are considered legal under the governing State law? Yes No

SECTION V – DELTA-8 THC AND OTHER THC & ADULT-USE CANNABINOIDS

If Delta-8 or other novel cannabinoid-containing products (e.g. Delta-10, THC-O, THC-V, THC-A, HHC, etc.), are sold by or on behalf of the Applicant, please confirm the following questions. N/A

27) All cannabinoid-containing products are extracted from legally cultivated hemp and manufactured solely in the US? Yes No

28) Does the Applicant attest that cannabinoid-containing products are hemp-derived and are NOT marijuana-derived? Yes No

29) Do all products contain **less than** 0.3% Delta-9 THC on a dry weight basis? Yes No

30) Has the Applicant ever a favorable legal opinion regarding the sale of Delta-8/other adult use cannabinoids in the governing state? Yes No

31) Are products shipped or sold to states or venues with an unfavorable legal opinion regarding the sale of Delta-8/other adult use cannabinoids? Yes No

32) Do any products contain caffeine? Yes No

33) If products are tested and certified by a third-party laboratory, please describe the testing and quality control procedures conducted to verify the safety and quality?

34) Do all packaging/labels and marketing materials include warnings for intoxicating effects and directions for use? Yes No

35) Is on-site consumption permitted on the Applicant's premise(s)?
If Yes, please list the type of products being consumed below: Yes No

SECTION VI – LABELING, MARKETING, AND ADVERTISING

36) Has legal counsel reviewed the labeling, advertising, and marketing materials and confirmed they are in compliance with the regulations established by the FDA and FTC? Yes No

37) Has the FDA or FTC ever contacted the Applicant about the labeling, advertising, and marketing materials?
If Yes, please provide details and attach to the application. Yes No

38) Do all labels include a disclaimer that the FDA has not evaluated the claims on the labels and that the products are not intended to diagnose, treat, cure or prevent any disease? Yes No

39) Does the Applicant make any structure/function claims, or any disease claims for specific health conditions on the products on labels, websites or other marketing materials?
If Yes, please provide specifics below and advise if documents substantiating each claim are maintained. Yes No

- 40) Does any of the packaging, marketing material, and any other literature appeal to children (e.g. packaging that looks like candy, juice boxes, cookies, toys, etc.)? Yes No
 If Yes, please provide packaging details on warnings designed to prevent access to minors in the general fill area at the end of the application.

SECTION VII – YOUR QUALITY CONTROL AND REGULATORY COMPLIANCE

- 41) Product Withdrawal/Product recall:
- a. Is there a formal written product recall procedure? Yes No
 If No, what is the anticipated date that a plan will be in place?
- b. Has there ever been a voluntarily or involuntarily recall or withdrawal, or is it anticipated that there will be a recall or withdrawal of any products for any reason? Yes No
 If Yes, please provide details:
- 42) Quality Assurance Program (QAP)/Quality Control Program (QCP):
- a. Is there a formal written Quality Assurance Program/Quality Control Program, including written Standard Operating Procedures that control operations? Yes No
- b. Please provide name, title and contact information (email/phone) for Quality Assurance Program/Quality Control Program manager:
- 43) Are all facilities used to manufacture, process, pack, hold or store products registered with the FDA? Yes No

SECTION VIII – REGULATORY EVENTS

- 44) In the past five (5) years, has the Applicant submitted a Serious Adverse Event Report (SAER) to the FDA or has the FDA notified the Applicant 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.
- 45) Is there a SOP detailing how to identify and handle a SAER/SAE? Yes No
- 46) Has the Applicant been inspected by the FDA? Yes No
- a. Did the FDA issue a Form 483 or Warning Letter notifying the Applicant of any objectionable conditions? Yes No
 If Yes, please provide a copy and the Applicant's written response to the FDA.
- b. Has the FDA issued a closeout letter in response to any Form 483 or Warning Letters? Yes No

SECTION IX – OPTIONAL COVERAGE ENHANCEMENTS

HIRED & NON-OWNED AUTO

N/A

- 47) If the Applicant desires Hired & Non-Owned Auto Liability (HNOA) coverage, please complete the below.
- a. Does the Applicant have a Commercial Auto Liability policy for the business? Yes No
- b. Are there any autos registered to and owned by the Applicant for business use? Yes No
- c. Will the Applicant 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

(Note: If "Yes" was answered to any of the questions within 47) a.- e., HNOA coverage will be unavailable.)

CYBER LIABILITY

N/A

48) If the Applicant desires Cyber Liability coverage, please complete the below.

- | | | |
|---|-----|----|
| a. Does the company configure firewalls to restrict inbound and outbound network traffic to prevent unauthorized access to internal networks? | Yes | No |
| b. Does the company update (e.g., patch, upgrade) commercial software for known security vulnerabilities per the manufacturer's advice? | Yes | No |
| 49) Does the Applicant's third-party technology service provider meet the regulatory provisions required by your company (e.g., PCI-DSS, HIPAA, SOX, etc.)? | Yes | No |
| a. Does the Applicant's website have a "payment cart"? | Yes | No |
| b. Does the Applicant collect medical information? | Yes | No |

(Note: If the Applicant answered "No" to questions 49) a. and b., or has a payment cart that is not PCI-DSS compliant or collects medical information, Cyber Coverage will be unavailable.)

HUMAN CLINICAL TRIALS

N/A

50) If the Applicant desires Human Clinical Trials coverage, please include a copy of the Informed Consent & Protocol documents and complete the below.

Note: Coverage is only available for Phase 1 and Phase 2 Trials, including any research and development performed in conjunction with the planned research trial.

- | | | |
|---|-----|----|
| a. Are signed contracts utilized between the Applicant and any Principal Investigators or Trial Sponsors? | Yes | No |
| b. Does the Applicant require all Principal Investigators to carry their own Products Coverage? | Yes | No |
| c. Does the Applicant require all subcontractors providing services in connection with your trial to carry their own Professional Liability Insurance Coverage? | Yes | No |
| d. Does the Applicant require all participants to sign an informed consent document? | Yes | No |
| e. Are all of the Applicant's clinical trials approved and subject to oversight by an Institutional Review Board? | Yes | No |
| f. Are the Applicant's Principal Investigator and Institutional Review Board related to the Sponsor? | Yes | No |

51) Please describe the following details for the Applicant's Clinical Trial:

- a. Overall Trial Description:
- b. Name of the Trial:
- c. Products being tested:
- d. Number of participants:
- e. Trial Dates/Length of Trial:

(Note: If the Applicant answered "No" to questions 50) a., b., and d., or "Yes" to question 50) f., Human Clinical Trials Coverage will be unavailable.)

SECTION X – LOSS HISTORY DETAILS

- | | | |
|---|-----|----|
| 52) Have there been any insured or uninsured losses and/or claims in the past five (5) years? | Yes | No |
| 53) Is the Applicant 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 the Applicant that are not listed in the five (5) years carrier loss history? If Yes, please attach a detailed explanation. | Yes | No |

54) Has any insurer cancelled coverage with the Applicant in the past five (5) years? Yes No
If Yes, please provide details including the reason why:

55) Current Carrier (check N/A if no current coverage) N/A

Is the current carrier offering renewal? Yes No

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

Limits: \$ Deductible: \$

Premium: \$ Rate: \$

56) 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 or any governmental body or ruling agency including but not limited to Steroids. Including any product, supplement, additive, substance, ingredient or compound controlled or banned by any governmental body or ruling agency or additions/changes to 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.

General fill-in area for further explanation:

Fraud Notices

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.

Other State Notices

Applicable in RI: THIS INSURANCE CONTRACT HAS BEEN PLACED WITH AN INSURER NOT LICENSED TO DO BUSINESS IN THE STATE OF RHODE ISLAND BUT APPROVED AS A SURPLUS LINES INSURER. THE INSURER IS NOT A MEMBER OF THE RHODE ISLAND INSURERS INSOLVENCY FUND. SHOULD THE INSURER BECOME INSOLVENT, THE PROTECTION AND BENEFITS OF THE RHODE ISLAND INSURERS INSOLVENCY FUND ARE NOT AVAILABLE.

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.