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WELLNESS APPLICATION

APPLICANT INFORMATION

Applicant Name:

Mailing Address:

City: State: Zip Code:

Location Address: (if different)

City: State: Zip Code:

Website: Proposed Effective Date:

Date Established: From: To:

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

Applicant is: ☐ Individual ☐ Joint Venture ☐ LLC

☐ Corporation ☐ Partnership ☐ Other - Specify:

YOUR OPERATIONS

1) Please list all acquisitions of companies and operations in the past 5 years

2) Description of operations/list products and goods:

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

a. Manufacturer _____ %

b. Contract-Manufacturer - Products sold under label of others _____ %

c. Wholesaler/Distributor – Products of others sold under label of others _____ %

d. Importer (Note: 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): _____ %

4) If you are a Manufacturer, Contract-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:*

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 PRODUCT SALES

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

9) 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	%	%

d. Do you currently have any or plan on having any weight loss, sexual health or body building products, or products containing the following:

- ☐ Aconite
- ☐ Bitter Orange
- ☐ Chaparral
- ☐ Colloidal Silver
- ☐ Coltsfoot
- ☐ Comfrey
- ☐ Country mallow
- ☐ Ephedra
- ☐ Germanium
- ☐ Kava
- ☐ Lobelia
- ☐ Magnolia
- ☐ Organ/Glandular Extracts
- ☐ Yohimbe

If yes, what percentage of your sales is applicable for each type of product and how many milligrams go into the products? Also provide the specific product names and labels of these products.

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

☐ Electronic cigarettes ☐ Vaping devices ☐ E-liquid ☐ Replacement batteries ☐ Battery rechargers

11) Do you promote any of your products for use in children? ☐ Yes ☐ No

If yes, please advise the product name, intended use, and sales:

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); or Kratom.

YOUR QUALITY CONTROL AND REGULATORY COMPLIANCE

12) 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:*

13) 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 Food, Drug & Cosmetic Act 21 CFR 111? ☐ Yes ☐ No

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

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

b. Do you have a formal written QAP/QCP, including written SOP's that control your operations? ☐ Yes ☐ No

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

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

16) Are you are 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 product? ☐ 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. 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? ☐ Yes ☐ No
***If no** to 15) d., coverage for CBD will not be available.*

17) 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 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

REGULATORY EVENTS

18) 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.*

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

20) 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.*

21) 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

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

OPTIONAL COVERAGE ENHANCEMENTS

23) 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.*

YOUR CLAIMS, LOSSES, DEMANDS FOR DAMAGES AND SIMILAR EXPERIENCE

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

24) Are you aware of any investigation, incident, condition, circumstance, lawsuit, legal action or suspected defect in any product or work, which has resulted or 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 attach a detailed explanation.*

25) Current Carrier:

Is current carrier offering renewal? ☐ Yes ☐ No

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

Limits: $ Deductible: $

Premium: $ Rate: $

26) 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 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.

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:

Title:

Current Date:

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

Signature of Applicant or Authorized Representative:

Title:

Current Date:

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

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

SOP means Standard Operating Procedure

cGMP / GMP means Current Good Manufacturing Practices / Good Manufacturing Practices

Cannabidiol (CBD) is a non-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: