

## YOUR INSTRUCTIONS

1. Answer all questions. If the answer to any question is NONE, please state NONE.
2. Application must be signed and dated by owner, partner or officer.
3. Please be certain all attachments are included as requested or where required.
4. If additional space is required, please feel free to attach a separate spreadsheet to elaborate your answers to any of our questions below.

## APPLICANT

1. Full name and description of operations of all entities to be named insured:

2. Business location and mailing address (please attach a separate sheet listing all locations in which you have operations and specify business operations at each location):

Street: \_\_\_\_\_

Mailing: \_\_\_\_\_

City: \_\_\_\_\_ County: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_

3. Contact Person: \_\_\_\_\_ Position: \_\_\_\_\_

Phone No.: \_\_\_\_\_ Fax No.: \_\_\_\_\_

Website address: \_\_\_\_\_ Email: \_\_\_\_\_

4. ☐ Individual ☐ Partnership ☐ Corporation ☐ Other: \_\_\_\_\_

5. Organization

a. Length of time in business under the present name: \_\_\_\_\_

b. Have you ever engaged in this or similar enterprises under a different name? ☐ Yes ☐ No

If yes, please provide details:

- c. If you are a subsidiary of another corporation, identify the parent corporation:

Does any insurance purchased by the above-described parent corporation(s) afford any coverage to you? ☐ Yes ☐ No

If yes, please detail: \_\_\_\_\_

- d. Considering any mergers, acquisitions or divestitures? ☐ Yes ☐ No
- e. Any mergers in the last 5 years? ☐ Yes ☐ No
- f. Any acquisitions in the last 5 years? ☐ Yes ☐ No
- g. With liabilities? ☐ Yes ☐ No
- h. Any divestitures in the last 5 years? ☐ Yes ☐ No

Explain all "Yes" responses:

6. Proposed effective date of insurance: \_\_\_\_\_
- a. Retroactive date requested: \_\_\_\_\_
- b. Has continuous claims made coverage been in effect since the retroactive date requested?  
☐ Yes ☐ No
- c. Limit of Liability requested: \_\_\_\_\_
- d. Deductible / SIR requested: \_\_\_\_\_

## PRODUCT

### SALES & DISTRIBUTION

1. List dollar value of total gross sales of your products for the past 5 years including a dollar estimate of gross sales for the upcoming policy year:

Year	Gross Receipts

2. What is your annual payroll? \_\_\_\_\_

3. Please provide estimated sales (dollar amount or percentage of totals stated in Item 1 Gross Receipts) for the coming 12-month period, broken down as follows:

<b>A. Pharmaceutical Products</b>	<b>US Sales</b>	<b>International Sales</b>
i. Branded products under your own label		
ii. Generic products under your own label		
iii. Branded products manufactured for others (CMO)		
iv. Generic products manufactured for others (CMO)		
v. Branded products distributed for others		
vi. Generic products distributed for others		
<b>B. Over the Counter Products (OTC)</b>		
i. OTC products under your own label		
ii. OTC products distributed for others		
<b>C. Vitamins and Supplements</b>		
i. Products under your own label		
ii. Products manufactured for others (CMO)		
iii. Products distributed for others		
<b>D. Medical Devices</b>		
i. Implantable products under own label (In body > 30 Days)		
ii. Implantable products manufactured for others (In body > 30 Days) (CMO)		
iii. Implantable products distributed for others (In body > 30 Days)		
iv. Invasive products under own label		
v. Invasive products manufactured for others (CMO)		
vi. Invasive products distributed for others		
vii. Non-Invasive products under own label		
viii. Non-Invasive products manufactured for others (CMO)		
ix. Non-Invasive products distributed for others		
x. Diagnostics under your own label		
xi. Diagnostics manufactured for others (CMO)		
xii. Diagnostics distributed for others		
<b>E. Contract Research Organization Services</b>		
<b>F. Other</b>		
<b>Total Estimated Sales</b>		

4. Please list your top 10 products and provide estimated sales for the next 12 months:

Products	Estimated Sales
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

5. Hemp / CBD Exposures

- Do you have cannabinoid products in your portfolio or plan on offering such products within the next 12 months? ☐ Yes ☐ No
- Are all cannabis products Hemp derived? ☐ Yes ☐ No
- Do these products contain 0.3% or less of THC? ☐ Yes ☐ No
- Do these products contain natural or synthetic isomers of THC in an amount that may cause intoxication? ☐ Yes ☐ No
- Do these products contain any cannabinoids in an amount that may cause intoxication? ☐ Yes ☐ No
- Is the insured involved with marijuana? ☐ Yes ☐ No

6. Weight Loss Exposures

- Do you currently manufacture or distribute GLP-1s? ☐ Yes ☐ No  
If yes, please provide details: \_\_\_\_\_

7. Confirm that you have never manufactured or distributed Phentermine, Fenfluramine and / or Dexfenfluramine. \_\_\_\_\_

8. Does your product line include the manufacture or distribution of any product intended for consumption by children under 12 years of age? ☐ Yes ☐ No

If yes, please identify the product and sales for each and whether you manufacture or distribute:

9. Do you provide any maintenance or repair services for any of the products it sells or distributes? ☐ Yes ☐ No

If yes, please describe and provide annual payroll figures for these services over the past three years:

10. Does your product line include the manufacture or distribution of any vaccine intended for human or animal use? ☐ Yes ☐ No

If yes, please identify the product and sales for each and whether you manufacture or distribute:

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### REGULATORY & SAFETY MONITORING

1. Do you have a full-time quality control manager that reports to senior management? ☐ Yes ☐ No
2. Do you maintain quality control procedures? ☐ Yes ☐ No
3. Do you maintain samples of products involved in your control procedures? ☐ Yes ☐ No

If yes, how long are samples retained?

4. Do any of your products require Black Boxed Warning or REMS program? ☐ Yes ☐ No

If yes, please detail:

5. Have you had any Class I Recalls within the past 3 years? ☐ Yes ☐ No

If yes, please detail:

6. Do you have a formal recall plan? ☐ Yes ☐ No

If yes, please describe or provide a copy:

7. Have any of your products been discontinued for any reason? ☐ Yes ☐ No

If yes, please detail:

8. Please provide top 3 products with Adverse Events Reported, if any.

9. Are all the products presently manufactured or distributed by you approved for sale in the United States by the United States Food & Drug Administration? ☐ Yes ☐ No

If not, please identify each such product and state the reason(s) why they are not approved for sale.

10. Within the past 3 years, have you had FDA inspections that resulted in any 483s or warning letters?

☐ Yes ☐ No

If yes, please detail:

11. Contaminates:

a. Benzene

- i. Does your portfolio contain products with Benzoyl Peroxide? ☐ Yes ☐ No
- ii. Does your portfolio contain sunscreen products? ☐ Yes ☐ No
- iii. Do your products contain carbomers with benzene? ☐ Yes ☐ No
- iv. If yes, are you looking to phase out the usage of carbomers with benzene in your products?  
☐ Yes ☐ No
- v. Do you test products for presence of benzene? ☐ Yes ☐ No
- vi. If yes, how often are products being tested for benzene, and/or other contaminants?

b. Per- and polyfluoroalkyl substances (PFAS)

- i. Do your products contain PFAS? ☐ Yes ☐ No
- ii. If yes, which products and what is the percentage of your total revenue said product(s)?

- iii. Do you test for the presence of PFAS, and / or other contaminants? ☐ Yes ☐ No

12. If yes, how often are products being tested for PFAS, and/or other contaminants?

c. Nitrosamine

- i. Do you test for the presence of Nitrosamines (and / or derivatives thereof), N,N-Dimethylformamide (and / or derivatives thereof) in your products? ☐ Yes ☐ No
- ii. If yes, how often are products being tested for Nitrosamines (and / or derivatives thereof), N,N-Dimethylformamide (and / or derivatives thereof), and / or other contaminants?

- iii. Are your testings performed in accordance with standards established by the FDA for Nitrosamine and its derivatives? \_\_\_\_\_

## CONTRACTS

1. Do you obtain certificates evidencing products liability insurance from suppliers? ☐ Yes ☐ No
2. Do you obtain certificates of insurance from manufacturers of products you distribute naming you as a vendor? ☐ Yes ☐ No Please explain any "NO" answer:  
\_\_\_\_\_
3. Do you give or obtain hold harmless or indemnity agreements from your suppliers or manufacturers of your products? ☐ Yes ☐ No  
If yes, please attach a copy of each.
4. For products you distribute or manufacture for others, do you have contracts in place that contain hold harmless or indemnity agreements? ☐ Yes ☐ No  
If yes, please attach a copy of each.

## HUMAN CLINICAL TRIALS

1. Do you anticipate any human clinical trials within the next 12 months? ☐ Yes ☐ No  
If so, please provide the following information (please attached a separate sheet if necessary):

Products & Indication	Indicate phase of trial and where tested	Commencement dates & expected length of trial	Projected ages, conditions of, number of patients for entire trial	Number of patients to be enrolled during policy term

2. Do any of your trials include pediatric / minor test subjects? ☐ Yes ☐ No  
If yes, please provide details:

3. Please provide sample copies of study Protocol and Informed Consent Form for adult and pediatric trials.
4. Have any of your trials been suspended or discontinued for any safety reasons? ☐ Yes ☐ No

If yes, please provide details:

5. Are all anticipated trials or studies conducted by independent third-party investigators? ☐ Yes ☐ No

6. If yes, please provide details:

7. If no, please provide details:

### CLAIMS HISTORY

1. Please provide loss run data for the past seven years, including amounts paid, details of losses, reserves and any claims or incidents reported to you:

Year	# Of Claims	Amount	Amount Reserved	Total Incurred

2. Please provide full details of any suit brought against you.

3. Are you aware of any claims not yet reported to your current / past carrier(s)? ☐ Yes ☐ No

If yes, please provide details:



4. Are you aware of any incidents or circumstances involving or arising out of the manufacture, distribution or repacking of any of your products that are likely to result in a claim(s) against you? ☐ Yes ☐ No

If yes, please provide details:

### HISTORICAL INFORMATION

1. Please identify each insurer that provided Products Liability Insurance to you over the past five years.

Policy Term	Company	Limits	Ded. / Sir	Premium	CM or Occ.	Retro Date (If Any)

2. Has any insurance company ever refused to issue or canceled Products Liability Insurance provided to you?

☐ Yes ☐ No

If yes, please explain:

Question 2 above is not applicable for Missouri domiciled insureds.

### IF EMPLOYEE BENEFITS IS TO BE COVERED, PLEASE SUBMIT THE FOLLOWING:

(This information MUST accompany this application or no coverage will be affordable.)

1. Completed and signed Employee Benefits Liability application.
2. Retro date of current EBL coverage if claims made.
3. Loss history.

### PLEASE ATTACH THE FOLLOWING INFORMATION TO THIS APPLICATION:

1. 5 years of currently valued prior carrier loss runs (no older than 90 days from the effective date)
2. Current Audited Financial Statement
3. Copies of all brochures, written statements, instructions, labels that accompany your products.
4. Copy of your most recent inspection or warning letters by the FDA and / or any other authorities, your response to such reports, and remedial action plans that resulted from such inspections or investigations.

## FRAUD WARNINGS

**GENERAL:** 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.

**The fraud warnings listed below are applicable in the following states: AL, AZ, AR, CA, CO, DC, FL, ID, KY, LA, ME, MD, NJ, NM, NY, OH, OK, OR, PA, TN, VT, VA, WA or WV. If you are located in one of these states, please take time to review the appropriate warning prior to submitting your claim.**

**ALABAMA:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or who knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution, fines, or confinement in prison, or any combination thereof.

**ARIZONA:** For your protection Arizona law requires the following statement to appear on this form: Any person who knowingly presents a false or fraudulent claim for payment of a loss is subject to criminal and civil penalties.

**ARKANSAS:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**CALIFORNIA:** For your protection, California law requires the following to appear on this form: Any person who knowingly presents a false or fraudulent claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

**COLORADO:** 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.

**DISTRICT OF COLUMBIA:** WARNING: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

**FLORIDA:** 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.

**IDAHO:** Any person who knowingly, and with intent to defraud or deceive any insurance company, files a statement of claim containing any false, incomplete, or misleading information is guilty of a felony.

**KENTUCKY:** Any person who knowingly and with intent to defraud any insurance company or other person files a 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.

**LOUISIANA:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**MAINE:** 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, or a denial of insurance benefits.

**MARYLAND:** Any person who knowingly and willfully presents a false or fraudulent claim for payment of a loss or benefit or who knowingly and willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**NEW JERSEY:** Any person who knowingly files a statement of claim containing any false or misleading information is subject to criminal and civil penalties.

**NEW MEXICO:** ANY PERSON WHO KNOWINGLY PRESENTS A FALSE OR FRAUDULENT CLAIM FOR PAYMENT OF A LOSS OR BENEFIT OR KNOWINGLY PRESENTS FALSE INFORMATION IN AN APPLICATION FOR INSURANCE IS GUILTY OF A CRIME AND MAY BE SUBJECT TO CIVIL FINES AND CRIMINAL PENALTIES.

**NEW YORK:** 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 shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.

**OHIO:** Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

**OKLAHOMA:** WARNING: Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes any claim for the proceeds of an insurance policy containing any false, incomplete, or misleading information is guilty of a felony.

**OREGON:** Any person who knowingly and with intent to defraud or solicit another to defraud an insurer: (1) by submitting an application, or (2) by filing a claim containing a false statement as to any material fact thereto, may be committing a fraudulent insurance act, which may be a crime and may subject the person to criminal and civil penalties.

**PENNSYLVANIA:** 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 act, which is a crime and subjects such person to criminal and civil penalties. **TENNESSEE:** It is a crime to knowingly provide false, incomplete, or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**VERMONT:** Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

**VIRGINIA:** It is a crime to knowingly provide false, incomplete, or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**WASHINGTON:** 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, or denial of insurance benefits.

**WEST VIRGINIA:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

The undersigned represents that the statements set forth in this Application are true and correct. The undersigned agree that the information provided in this Application and any material submitted herewith are the basis for issuance of the insurance Policy. The undersigned further agree that the Application and any material submitted herewith shall be considered attached to and a part of the Policy.

The undersigned further agrees:

- If the undersigned discovers or become aware of any material change which would render the Application inaccurate or incomplete between the date of this application and the Policy inception date, the undersigned must provide notice of such change in writing to the insurer as soon as practicable.
- Any Policy issued will be in reliance upon the truthfulness of the information provided in this Application.
- The signing of this Application does not bind the Applicant to purchase insurance.

**Application must be signed and dated by a principal, partner, officer or director of the firm.**

Your Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Title: \_\_\_\_\_

PLEASE NOTE: COMPLETION AND SUBMISSION OF THIS APPLICATION IS FOR THE PURPOSE OF SECURING A PREMIUM QUOTATION ONLY.

Agent or Broker: \_\_\_\_\_

Email: \_\_\_\_\_

Telephone: \_\_\_\_\_