

HANOVER HUSION

# **Supplemental Application**

# UNDERWRITTEN BY: THE HANOVER INSURANCE COMPANY CLAIMS MADE NOTICE

THIS POLICY PROVIDES COVERAGE ON A CLAIMS-MADE BASIS. SUBJECT TO ITS TERMS, THIS POLICY APPLIES ONLY TO "CLAIMS" FIRST MADE AGAINST "YOU" DURING THE "POLICY PERIOD", AUTOMATIC EXTENDED REPORTING PERIOD OR ANY PURCHASED OPTIONAL EXTENDED REPORTING PERIOD THAT MAY APPLY. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

### "CLAIM EXPENSE" WITHIN LIMITS

THIS CLAIMS-MADE POLICY PROVIDES FOR "CLAIM EXPENSE" PAYABLE WITHIN, AND NOT IN ADDITION TO, THE LIMITS OF INSURANCE. "CLAIM EXPENSE" WILL REDUCE AND MAY EXHAUST THE LIMIT OF INSURANCE AND WILL BE APPLIED AGAINST THEDEDUCTIBLE. PLEASE READ THE POLICY CAREFULLY TO DETERMINE RIGHTS, DUTIES, COVERAGE AND COVERAGE RESTRICTIONS.

## **APPLICATION INSTRUCTIONS**

Please answer all required sections of questions completely. The following sections are required for all applicants: General Information, Products-Completed Operations Liability, and Products-Completed Operations—Regulatory and Risk Management. Select the additional coverage options you would like to apply for by completing all the required questions for each coverage.

Whenever used in this Application, the term you or your(s) or the Applicant shall mean the Named Insured and all subsidiaries, unless otherwise stated.

### I. GENERAL INFORMATION

## A. YOUR BUSINESS OPERATIONS

- 1. Name of Applicant:
- 2. Address of Applicant:
- 3. Website Address:
- 4. Years in Business?
- 5. Please list all your subsidiaries and your percentage of ownership in each:

	6.	Are you in compliance with all applicable regulatory guidelines?	□Yes	□No
в.	AP	PLICANT INSURANCE INFORMATION		
		ve you discontinued or ceased to provide any products, services or operations in the t 12 months?	□Yes	□No
	a.	If Yes, please provide details:		
	b.	And if Yes, do you provide continuing services, support or other remedies for discontinue products, services or operations? If Yes, please provide details:	ed □Yes	□No

# C. REQUESTED INSURANCE PROGRAM

Please provide information on your requested insurance program:

COVERAGE	Limits	Deductible	Retroactive Date(s)
Products-Completed Operations Liability	\$	\$	
Errors & Omissions	\$	\$	
Information Security	\$	\$	
Privacy and Personal Injury	\$	\$	
Media and Content	\$	\$	
Data Breach Expense	\$	\$	
Products Recall Expense	\$	\$	
Human Clinical Trial Expense	\$		

- 1. Describe any new products or services entering the market that are substantially different in scope or end use than your current products or services?
- Do you anticipate any significant changes in the nature of your business over the next 12 months?

□Yes □No

If Yes, please provide details:

3. Please provide a breakdown of your revenue:

SOURCES OF REVENUE	Current Annual Revenues	Projected Annual Revenues
Total U.S. Revenue		
Total Foreign Revenue		
Total Revenue		

4. Please provide a breakdown of your products or services by percentage of your total revenue:

SOURCES OF REVENUE	Projected Annual Revenues
Pharmaceuticals / Biologics	%
Dietary Supplement	%
Medical Devices	%
Digital Health	%
Contract Research Organization and/or Research Institute	%
Other:	%

5.	Do you have any association, past or present, with banned products?	□Yes □No
	If Yes, please provide details:	
6.	Have any of your products, services or organizations been subject to an investigation by any U.S. or foreign government agency?	□Yes □No
	If Yes, please provide details:	
7.	Do you import any products or ingredients?	□Yes □No
	If Yes, what products/ingredients and what countries?	

Please check the box if you have studies or products (past, present, or planned) involving any of the following classes of products:

Addictive Substance/Opioids	Radiation Emitting Technologies
Birth Control or Fertility	SSRIs or SNRIs
Gene Therapy Known	Steroids
Hormone Replacement Products	Vaccines
HPAPIs or HPAIs	Weight Management
Cannabis	Generic Pharmaceuticals
Known Carcinogen	Mesh
Known Mutagen	Knee Replacement and components
Teratogen	Hip Replacement and components
Mercury	Shoulder replacement and components
Pediatric/Minors/Pregnant Women	Generative Artificial Intelligence
Metal on metal implants	

### D. HISTORY

1. Within the past 5 years:

a.	Have you received any allegation(s), claims or suits (insured or not) claiming
	defect of kind and/or damages associated with your products, services or human
	clinical trials?

- b. Have you given notice of any claim, circumstance or potential claim to any insurer under any insurance coverage referred to above?
- c. Are you aware of any facts or circumstances associated with your products or services that could reasonably be expected to result in a claim or suit?
- d. Have you experienced or has your system or website been used in any type of security incident or attack (e.g. viruses, denial of service attacks, etc.)?

## II. PRODUCTS COMPLETED OPERATIONS LIABILITY

### A. PHARMACEUTICALS/BIOLOGICS

(Please complete this section if you manufacture or distribute a pharmaceutical. If you do not, please skip this section.)

□Yes □No

□Yes □No

Yes No

□Yes □No

1. Please provide a breakdown of your product revenue by product type and number of units sold:

ROUTE OF ADMINISTRATION	Prescription	Generic	Over The Counter	Percentage of Revenue Sold	Number of Units Sold
Topical				%	
Oral				%	
Inhalable				%	
Injectable				%	
Transdermal				%	
Drug Delivery				%	
Other				%	

2. Please check the box where you have studies, products, or services (past, present or future) involving any of the following specific pharmaceutical products:

Accutane	Fenfluramine	Pioglitazone
Acetaminophen	Gadolinium	Proton Pump Inhibitors
Anabolic steroids	Gamma-hydroxybutyrate (GHB), Gamma Butyrate (GBL), 1,4 Butanediol (BD)	Pseudoephedrine
Androstenedione	Hormone Replacement Products	Redux
Aristochochic acid	Isotretinoin	Rosiglitazone
Benzodiazepines	Kratom	Selective Serotonin Reuptake Inhibitors (SSRI)
Birth control products	Mercury	Statins
Bismacine	Metoclopramide	Talc
Bisphosphonate	Opioids	Testosterone
Cannabis	Phenibut	Thalidomide
Cisapride	Phentermine	Thimerosal
Cox-2-inhibitors	Phenylpropanolamine (PPA)	Troglitazone
Di-(2-ethylhexyl) Phthalate (DEHP)	Phospho soda, sodium phosphate, o any phosphor soda or sodium phosphate based agents	Usnea and usnic acid
Diethylstilbestrol (DES)		

### **B. DIETARY SUPPLEMENTS**

Please check the box where you have studies, products, or services (past, present or future) involving any of the following specific dietary supplements:

1,3 Dimethyl amylamine (DMAA)	Colloidal silver	Kratom
1,3 Dimethyl butylamine (DMBA)	Di-(2-ethylhexyl) Phthalate (DEHP)	Lobelia
1,4 Dimethyl pentylamine (DMHA)	Ephedra	Magnolia
Anabolic steroids	Ephedrine	Phenibut
Androstenedione	Fenfluramine	Piper Methysticum (Kava)
Aristochochic acid	Gamma-hydroxybutyrate (GHB), Gamma Butyrate (GBL), 1,4 Butanediol (BD)	Proton Pump Inhibitors
Bitter orange	Germander	Testosterone
β-Methylphenethylamine (BMPEA)	Hormone Replacement Products	Usnea and usnic acid
Chaparrel	Jin Bu huan	Yohimbe

### C. MEDICAL DEVICE

(Please complete this section if you manufacture, assemble, distribute or provide service to components and/or finished goods related to medical devices, biotechnology products or laboratory products/technologies. If you do not, please skip this section.)

1. How would you define yourself? Please check all the boxes(es) below that apply:

Medical Device Medical Device Consumables Laboratory Analytical Equipment and Technologies

Biotechnology Products or Consumables (excludes anything administered into the body)

2. Please provide a breakdown of your revenue-by-revenue source:

SOURCE OF REVENUE	For Yourself	For Others	Percentage of Total Revenue
Component manufacturer of a product	%	%	%
Contract manufacturer of a product	%	%	%
Manufacturer of a product	%	%	%
Distributor of a product	%	%	%
Installer, service or repairer of a product	%	%	%
Refurbisher of a product	%	%	%
Other:	%	%	%

3. Please check the box below where you have any past, present or planned involvement associated with any of the following:

Aerospace or aircraft	Implantable medical device
Automotive	Industrial automation
Biologics	Latex
Defense or military	Life sustaining or life supporting medical device
Drug delivery system	Physical security devices

If you checked any of the boxes above, please provide an explanation describing your product or work below:

# D. DIGITAL HEALTH

(Please complete this section if you provide digital products. If you do not, please skip this section.)

1. Please check all the activities below that apply to your company and the end use environment(s) for your products:

	PRODUCT END USE ENVIRONMENT(S)								
PRODUCTS	Clinical	Pharmacy	Laboratory	Home	Mobile				
Electronic, Health, Electronic Medical or Personal Health Record									
E-Prescriptions									
Clinical Decision Support									
Computerized Physician Ordering Entry									
Drug to Drug Interactions									
Health Kiosk									
HIPAA Compliance Software/Advisory/Services									

Medication Coding or Dispensing			
Medical, Health or Nutritional Content/Advisory/Services			
Patient Archiving Capturing System			
Patient or Clinical Communication Portal			
Patient Management Software			
Remote Medical Education for Clinicians			
Remote Patient Monitoring			
Unregulated FDA Mobile Applications			
Other:			

# E. CONTRACT RESEARCH

(Please complete this section if you operated as a clinical or contract research organization and/or a research institute. If you do not, please skip this section.)

1. How would you define yourself? Please check the box(es) that apply:

Pre-Clinical Contract Research Organization
Clinical Research Organization
Research Institute

2. Please check all the activities below that apply to your company:

PRE-CLINICAL	For Yourself	For Others	CLINICAL	For Yourself	For Others
Bench Research			Protocol and/or consent form development		
Medicinal chemistry including target discovery and validation			Clinical trial management and/or data collection		
Lead optimization and validation			Regulatory support and/or statistical analysis		
In vitro screening			Pharmacovigilance		
Animal studies			Medical or pathology services performed onsite		
Toxicology and/or pathology			Licensing of technology, intellectual property or data to others		
Other:			Providing clinical instructions to others		
Other:			Other:		

# F. CLINICAL TRIALS

(Please complete this section if you are or plan to conduct a clinical trial. If you do not, please skip this section.)

1. Please list your clinical trials, present and planned, for the next 12 months:

PRODUCT NAME & PROTOCOL NUMBER	# of New Subjects to be Enrolled Over the Next Policy Period		Clinical Trial Phase (I, II, III, or IV)	Countries Where the Trial Takes Place
Diagon ottoch on IDP or	aproval clinical trial pro	tocol and informed a	noont dooumont fa	r all aliginal trials

Please attach an IRB approval, clinical trial protocol and informed consent document for all clinical trials scheduled to occur over the next 12 months.

2.	How many clinical trials have you sponsored in the last 3 years?		
3.	What is the total number of human subjects enrolled in the last 3 years?		
4.	What is the total number of expanded access or compassionate use subject participants antic over the next 12 months?	cipated	
5.	Have any of your clinical trials been classified as significant risk by the FDA or IRB?	□Yes	□No
	If Yes, please provide details:		
6.	Have any of your clinical trials been suspended or discontinued in whole, or in part, because of safety reasons?	□Yes	□No
	If Yes, please provide details:		
7.	What is the number of clinical trial "For Cause Audits" conducted by you or a regulatory agend in the last 5 years?	cy ∐Yes	□No
	If Yes, please provide details:		
8.	Have any clinical investigators been cited for regulatory violations?	□Yes	□No
	If Yes, please provide details:		
9.	Do you ever act as both trial sponsor and clinical investigator?	□Yes	□No
	If Yes, please provide details:		
10.	Do you ever provide material or product for investigator sponsored trials?	Yes	□No
	If Yes, please provide details:		
11.	Do you have formalized Clinical Trial Suspension Standard Operating Procedure (SOPs) in place?	□Yes	□No
12.	Do you provide Clinical Investigators, CROs or Sites with compensation other than charges for specific services rendered (e.g., enrollment bonuses, equity interest)?	□Yes	□No
13.	What is the maximum compensation you have offered trial participants?	_	
70-014	40 06/24 The Hanover Insurance Group   440 Lincoln Street, Worcester, MA 01653	Page 7	7 of 12

# III. PRODUCTS COMPLETED OPERATIONS - REGULATORY AND RISK MANAGEMENT

## A. REGULATORY

	safety warning to an existing label or instruction manual in the last 5 years? If Yes please provide details:	
3.	Do you have any outstanding FDA issues?	□Yes □No
	If Yes, please provide details:	
4.	Have you been cited by any other regulatory agency (other than the FDA) for deficiencies and/or for noncompliance in the last 12 months?	s □Yes □No
	If Yes, please provide details:	

(Please complete this section if you are applying for Errors & Omissions coverage.) Contract Information and Contract Risk Management

1. Do you require a written contract, with your customers, for your products or services?

If Yes, please provide a breakdown of your contract activities below:

TYPE OF CONTRACT	What Percentage is Standard/Non-Deviating	What Percentage is Customized To Meet Customer Requirements
Formal Contract	%	%
Licensing Agreement	%	%
Purchase Order	%	%
Other	%	%

2. Do your standard contracts, licensing agreements or purchase orders contain the following provisions? Check all that apply:

Statement of Work	Exclusive Remedy	Performance Milestones/Schedule of Deliverables
Limitation of Liability	Integration Clause	Customer Maintenance Provision
Limitation of Consequential Damages	Force Majeure	Hold Harmless/Indemnification Agreement
Disclaimer of Warranties	Arbitration Clause	Conditions of customer acceptance of product or service

3. Describe your three largest customer contracts, purchase orders, licensing agreements or projects:

CUSTOMER NAME	Product or Service Provided	Size of Contract, Purchase Order, Licensing Agreement or Project	Length of Contract

4. In the past 12 months, have you made any changes to your customer contracts or

contracting procedures?

If Yes, please explain:

5. Please provide the following:

Size of average customer contract	\$ Length of average customer contract (# of months)	
Size of largest customer contract	\$ Length of largest customer contract (# of months)	

**Subcontractors** 

In the past 12 months, has your use of subcontractors changed?

□Yes □No

□Yes □No

If Yes, please explain changes:

# **B. CYBER SECURITY**

Indicate the type and number of unique records collected/maintained by you or others on your behalf. Check all that apply:

TYPE OF INFORMATION	Number of Records									
Biometric information		<50K		50K-500K		500K-1M		1M-3M		>3M
Financial account numbers		<50K		50K-500K		500K-1M		1M-3M		>3M
Other personally identifying information (i.e., social security numbers, passport numbers)		<50K		50K-500K		500K-1M		1M-3M		>3M
Protected Health Information		<50K		50K-500K		500K-1M		1M-3M		>3M
Credit card numbers		<50K		50K-500K		500K-1M		1M-3M		>3M
Other information not described above (i.e., name, address, telephone numbers, etc.		<50K		50K-500K		500K-1M		1M-3M		>3M

# Product or Service Cybersecurity

- 1. In the last 12 months, have you made any changes to your:
  - a. Network and information security policies?
    b. Disaster recovery plan?
    c. Facilities security measures?
    d. Network security measures?
    lYes No
    lYes No
    lYes No

2.	In t	In the past 12 months, did you many any changes to your contract agreements with vendors,						
	par	partners, subcontractors, independent contractors and other third parties regarding security						
	req	quirer	nents and responsibilities for sensitive and confidential information?	□Yes □No				
3.	Wh	nen e	mployee/contractors access critical systems, is multi-factor authentication utilized?	□Yes □No				
4.	Do	Do you use vendors for any of the following:						
	a.	Cus	stomer service?	□Yes □No				
	b.	We	b hosting/data center operations?	□Yes □No				
	c.	Fac	ilities security measures?	□Yes □No				
	d.	Net	work security measures?	□Yes □No				
		If you answered Yes, to any Vendor question above, please explain each Yes answer						
5.	Do	you	have a formal process for reviewing your vendor's information security procedures?					
6.	Do	you	use a standard contract or agreement with all vendors?	□Yes □No				
	lf Y	′es, a	are hold harmless and indemnification provisions in your favor?	□Yes □No				
7. Are your vendors required to carry Errors and Omissi			ur vendors required to carry Errors and Omissions insurance?	□Yes □No				
	Pe	al Injury Liability						
			you sell, collect or share personal and/or confidential information gathered from custo ers? (This includes information gathered from your website or by other means.)	mers or Yes No				
		If Yes, do you notify and obtain the consent of customers or others prior to dissemin this information?		□Yes □No				
			es, do you notify and obtain the consent of customers or others prior to collecting information?	∏Yes ∏No				
	2.	Do	you have a chat room, bulletin board or social media site?	□Yes □No				
			es, please provide the following information:					
			Who are the primary users of the chat room, bulletin board or social media site (i.e., ovendors, customers, etc.)?	employees,				
		b.	Do you monitor the chat room, bulletin board or social media site?	□Yes □No				
		c.	How quickly do you remove content and posts when you are notified they are unacce	eptable or				
			infringing?					

### **B. MEDIA AND CONTENT**

(Please complete this section if you are applying for Media and Content coverage.)

1. In the last 12 months, have you made any changes to your intellectual property clearance

	proce	edures?	□Yes □No
2.	. In the past 12 months:		
		Have you enforced or threatened to enforce your Intellectual Property Rights against a third party?	□Yes □No
		Has any third party notified you that you are infringing upon their Intellectual Property Rights?.	□Yes □No
	11		

If you answered Yes to either of these questions, please provide details:

## V. DECLARATION AND SIGNATURE

The undersigned, acting on behalf of all Applicants, declare that the statements set forth in this Application are true and correct and that thorough efforts were made to obtain requested information from each and every Applicant proposed for this insurance to facilitate the proper and accurate completion of this Application.

The undersigned agree that the information provided in this Application and any material submitted herewith are the representations of all the Applicants and are the basis for issuance of the insurance policy provided by us. Any material submitted with the Application shall be maintained on file (either electronically or paper) with us.

It is further agreed that:

- If any of the Applicants discover or become aware of any significant change in the condition of the Applicant
  Organization between the date of this Application and the policy inception date, which would render the
  Application inaccurate or incomplete, notice of such change will be reported in writing immediately;
- Any policy issued, will be in reliance upon the truthfulness of the information provided in this Application; provided, however, with respect to such information, no knowledge or information possessed by any Applicant shall be imputed to any other Applicants. If any person or persons knew as of the policy inception date that such information contained in the Application(s) were untrue, inaccurate or incomplete, then coverage may be denied or canceled if such information was material to issuance of the policy;
- Statements in the Application, facts pertaining to or knowledge possessed by the individual signing the Application shall be imputed to the Applicant; and
- The signing of this Application does not bind the undersigned to purchase insurance.

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

### ATTENTION APPLICANTS IN THE FOLLOWING JURISDICTIONS

ALABAMA, ARKANSAS, DISTRICT OF COLUMBIA, LOUISIANA, MARYLAND, NEW MEXICO, RHODE ISLAND AND WEST VIRGINIA: Any person who knowingly (or willfully in MD) presents a false or fraudulent claim for payment of a loss or benefit or knowingly (or willfully in MD) 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 false or fraudulent information to obtain or amend insurance coverage or to make a claim for 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.

**FLORIDA AND OKLAHOMA:** 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 in FL).

**KANSAS:** 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, electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or 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.

**KENTUCKY**, OHIO AND 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 insurance act, which is a crime and subjects such person to criminal and civil penalties.

**MAINE, TENNESSEE, VIRGINIA, AND 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 and denial of insurance benefits. \*Applies in ME Only.

**NEW HAMPSHIRE AND NEW JERSEY:** Any person who includes any false or misleading information to the best of her/his knowledge on an application for an insurance policy is subject to criminal and civil penalties.

**OREGON:** 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.

**PUERTO RICO:** 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.

**VERMONT FRAUD NOTICE:** 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.

**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 subjects such person to civil penalties not to exceed five thousand dollars and the stated value of the claim for each such violation.

This Application must be signed by a representative of the Applicant acting as the authorized representative of the person(s) and entity(ies) proposed for this insurance.

DATE:

SIGNATURE/TITLE

(Chief Executive Officer, President, Chief Financial Officer, Managing Partner or Owner)

Produced By:	Agent:	Agency:						
Agent Signature:								
Agency Taxpaye	r ID or SS No.:	Agent License Number:						
Address (Street, City, State, Zip):								