HAMILTON

Clear Form

LIFE SCIENCES GENERAL APPLICATION

Commercial General Liability | Products-Completed Operations | Professional Liability | Excess Liability

Required documents, in addition to this application:

- Five years of currently valued loss runs, with detail on any claim open or exceeding $25,000
- Product list or catalog, labeling/instructions for use, and marketing materials (if not on Applicant's website)
- Current declarations page(s), including retroactive date(s) for any claims-made coverage
- Most recent financial statement (if requested)

APPLICANT INFORMATION

Legal Name of Applicant:	
DBA / Trade Names:	
Mailing Address:	
Primary Location Address:	
Other Location Address(es):	

List all subsidiaries and/or additional named insureds and their operations:

Inspection / audit contact:	

Years in business:		**Website:**	

Type of Entity		
☐ Corporation	☐ Limited Liability Company	☐ Partnership
☐ Individual	☐ Joint Venture	☐ Other

COVERAGE REQUESTED

Proposed effective date:		**Proposed expiration date:**	

Coverage	**Limits**	**Deductible**	**Retroactive Date**
Commercial General Liability (Occurrence)	$	$	
Products-Completed Operations (Claims-Made)	$	$	
Professional Liability (Claims-Made)	$	$	
Excess Liability (Follow Form)	$	$	

Optional Coverages Requested:	☐ Product Withdrawal Expense	☐ Manufacturing E&O
☐ Hired & Non-Owned Auto	☐ Blanket Additional Insured	☐ Prop 65
☐ Other:		

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GENERAL INFORMATION

1. Please provide a description of your operations:

2. Provide sales and employee information:

Year	Domestic Sales	Foreign Sales	Payroll	# of Employees
Next year (est.)	$	$	$	
Current / last 12 months	$	$	$	
1st year prior	$	$	$	
2nd year prior	$	$	$	
3rd year prior	$	$	$	

3. List all products and services for which coverage is requested. Only those listed will be considered for coverage. (Attach additional pages if needed.)

Product / Service Description	Years in Market	% of Gross Sales	Operation (see codes below)	Sold to (see codes below)
		%		
		%		
		%		
		%		
		%		

Operation: ***M*** *= Manufacturer* ***CM*** *= Contract Manufacturer* ***PL*** *= Private Labeler* ***I*** *= Importer* ***W*** *= Wholesaler/Distributor* ***R*** *= Retailer* ***MR*** *= Mfr. Rep.* ***D*** *= Designer/Developer*

Sold to: ***M*** *= Manufacturers* ***W*** *= Wholesalers/Distributors* ***H*** *= Hospitals/Healthcare Providers* ***R*** *= Retailers* ***C*** *= Consumer Direct (incl. online)* ***O*** *= Other*

4. Percentage of sales by product type (should total 100%):

Cosmetics/personal care	%	Diagnostics/laboratory products	%
Medical devices/equipment	%	Non-FDA regulated wellness products	%
Nutraceuticals/dietary supplements	%	OTC pharmaceuticals	%
Other (describe in the space below)	%	Rx pharmaceuticals	%

5. Will any new products or services be introduced in the next 12 months? Yes ◯ No ◯

If Yes, describe and provide anticipated launch dates:

6. Have any products been discontinued in the past five years? Yes ◯ No ◯

If Yes, identify products and reason for discontinuation:

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7. Have any products or product lines been acquired by merger or acquisition?	Yes ◯	No ◯
If Yes, did the Applicant assume liability for previously sold products?	Yes ◯	No ◯

8. Does the Applicant:		
a. Rent, lease, refurbish, or resell used products or equipment?	Yes ◯	No ◯
If Yes, please provide the % of revenue:		%
b. Install, service, repair, or train on products at customer locations?	Yes ◯	No ◯
c. Sponsor, conduct, or supply product for any human clinical trial, currently or within the next 12 months?	Yes ◯	No ◯
d. Provide professional services to others for a fee (e.g., design, consulting, regulatory, research, training)?	Yes ◯	No ◯
e. Perform laboratory or testing services for others?	Yes ◯	No ◯
f. Develop or sell software, apps, or AI tools that diagnose, monitor, or direct treatment?	Yes ◯	No ◯

MEDICAL DEVICES (complete only if applicable)

9. Medical Device Classification (must total 100%):	
FDA Classification	% of Device Sales
Class I	%
Class II	%
Class III	%
Unclassified	%
TOTAL	**100%**

10. Device Characteristics (check all that apply):			
☐	Implantable (temporary or permanent)	☐	Used to diagnose, monitor, or direct treatment
☐	Life-sustaining or life-supporting	☐	Contains a drug, biologic, or software component
☐	In development, or pending FDA clearance/approval		

11. Do any devices contain latex or silicone?	Yes ◯	No ◯
12. Does the Applicant promote any device for off-label use?	Yes ◯	No ◯

PHARMACEUTICALS, NUTRACEUTICALS, OR COSMETICS (complete only if applicable)

13. Percentage of sales by route of administration:			
Oral / ingestible	%	Inhaled / vaporized	%
Topical	%	Injectable / implantable	%
Sublingual / other:	%	**TOTAL**	**100%**

14. Does the Applicant manufacture, distribute, or repackage any Rx drug, or hold a DEA registration?	Yes ◯	No ◯

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15. Do product labels or marketing include structure/function, health, efficacy, or disease claims?	Yes ◯	No ◯
16. Do labels include all required warnings, contraindications, and disclaimers (e.g., DSHEA, Prop 65)?	Yes ◯	No ◯
17. Are any products marketed for children, pregnant or nursing women, or the elderly?	Yes ◯	No ◯
18. Do any products contain an ingredient that is a drug, controlled substance, or restricted ingredient?	Yes ◯	No ◯
19. Are any products marketed for weight loss, sexual enhancement, or sports performance?	Yes ◯	No ◯
20. Has any product required a Black Box or other significant safety warning in the past five years?	Yes ◯	No ◯

REGULATORY

21. Are all registrations, licenses, clearances, and approvals required to manufacture and market the Applicant's products current and in good standing (FDA, DEA, state, or other)?	Yes ◯	No ◯
22. In the past five years, has the Applicant received an FDA Form 483, Warning Letter, Import Alert, seizure, consent decree, license suspension, or other regulatory enforcement action?	Yes ◯	No ◯
23. Date of last FDA or regulatory inspection:		

MANUFACTURING, SUPPLY CHAIN & QUALITY CONTROL

24. Does the Applicant design and manufacture the complete product?	Yes ◯	No ◯
25. Do others manufacture, assemble, or package products under the Applicant's name or label?	Yes ◯	No ◯
If Yes, are written quality / supply agreements in place?	Yes ◯	No ◯
26. Does the Applicant manufacture products sold under another entity's name or label?	Yes ◯	No ◯
27. Do any finished products, ingredients, or components originate outside the U.S.? If Yes:	Yes ◯	No ◯
a. Does the Applicant import directly?	Yes ◯	No ◯
b. Are imported goods tested or verified on receipt?	Yes ◯	No ◯
c. List countries of origin and % of sales:		
28. Does the Applicant obtain certificates of insurance evidencing Products Liability from all manufacturers and suppliers?	Yes ◯	No ◯
If Yes, is the Applicant named as an additional insured (vendor) on those policies?	Yes ◯	No ◯
29. Does the Applicant have a formal written quality control and testing program?	Yes ◯	No ◯
☐ *Certifications:* ☐ cGMP ☐ ISO 13485 ☐ ISO 9001 ☐ Other:		
30. Does the Applicant have a written records retention policy in place?	Yes ◯	No ◯
Record retention period:		

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31. Can products be traced by lot, batch, or serial number to the date of sale and purchaser?	Yes ◯	No ◯
32. Are product labels, instructions, and advertising reviewed by legal counsel before release?	Yes ◯	No ◯
33. Does the Applicant maintain written complaint handling and adverse event reporting procedures?	Yes ◯	No ◯
34. Does the Applicant have a written product recall plan?	Yes ◯	No ◯

INSURANCE, LOSS & PRODUCT HISTORY

35. Current and prior insurance (past three years):

Carrier	Coverage	Limits	Deductible	Premium	Retro Date	Policy Term
		$	$	$		
		$	$	$		
		$	$	$		

36. Has any insurance been cancelled, declined, or non-renewed in the past five years? (Not applicable in MO)	Yes ◯	No ◯
If Yes, please explain:		

37. Claims History:

Policy Year	# of Claims	Total Paid	Total Reserves	Total Incurred	Valuation Date

For any Yes answers to Questions 38-41 below, please provide detailed information in the Supplemental Information section of this application or provide separate attachments.

38. Has any product been recalled, withdrawn, or subject to a field correction, or is a recall being considered?	Yes ◯	No ◯
39. Have any serious injuries, deaths, or adverse events been reported to the Applicant or to the FDA (e.g., MAUDE, CAERS, FAERS) involving the Applicant's products?	Yes ◯	No ◯
40. Has any product or ingredient been the subject of a certified or attempted class action, MDL, or mass tort?	Yes ◯	No ◯
41. Is the Applicant aware of any fact, circumstance, or incident that may give rise to a claim or recall?	Yes ◯	No ◯

SUPPLEMENTAL INFORMATION

Please use this section to provide additional details for Questions 38-41, or for any other questions requiring additional space for answers.

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FRAUD WARNING

NOTICE TO ALABAMA, ALASKA, ARIZONA, ARKANSAS, CONNECTICUT, DELAWARE, GEORGIA, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NORTH CAROLINA, NORTH DAKOTA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING APPLICANTS: In some 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, for the purpose of misleading, conceals information concerning any fact material thereto, may commit a fraudulent insurance act which is a crime in many states.

NOTICE TO CALIFORNIA INSUREDS: 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 the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

NOTICE TO COLORADO APPLICANTS: 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 policy holder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claiming with regard to a settlement or award payable for insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

NOTICE TO DISTRICT OF COLUMBIA APPLICANTS: **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.

NOTICE TO FLORIDA APPLICANTS: Any person who knowingly and with intent to injure, defraud or deceive any insurance company files a statement of claim containing any false, incomplete or misleading information is guilty of a felony of the third degree.

NOTICE TO HAWAII APPLICANTS: For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both.

NOTICE TO KENTUCKY APPLICANTS: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance 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.

NOTICE TO LOUISIANA APPLICANTS: 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.

NOTICE TO MAINE APPLICANTS: 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.

NOTICE TO NEW JERSEY APPLICANTS: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

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NOTICE TO NEW MEXICO APPLICANTS: 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.

NOTICE TO NEW YORK APPLICANTS: Any person who knowingly and with intent to defraud an 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 $5,000 and the stated value of the claim for each such violation.

NOTICE TO OHIO APPLICANTS: Any person who, with intent to defraud or knowing that he/she 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.

NOTICE TO OKLAHOMA APPLICANTS: 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.

NOTICE TO PENNSYLVANIA APPLICANTS: Any person who knowingly and with intent to defraud any insurance company, or other person, files an application for insurance or statement of a 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 the person to criminal and civil penalties.

NOTICE TO TENNESSEE APPLICANTS: 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.

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

NOTICE TO APPLICANT: Coverage applied for is solely as stated in the policy. Products-Completed Operations and Professional Liability coverage is written on a claims-made basis and applies only to claims first made during the policy period or any applicable extended reporting period, subject to the retroactive date. Defense costs may be included within the limits of insurance.

The Applicant acknowledges that the answers provided herein are based on a reasonable inquiry and/or investigation. The Applicant warrants that the above statements and particulars together with any attached or appended documents are true and complete and do not misrepresent, misstate or omit any material facts.

The Applicant agrees to notify us of any material changes in the answers to the questions on this questionnaire which may arise prior to the effective date of any policy issued pursuant to this questionnaire and the Applicant understands that any outstanding quotations may be modified or withdrawn based upon such changes at our sole discretion.

Completion of this form does not bind coverage. Applicant's acceptance of the company's quotation is required prior to binding coverage and policy issuance.

All written statements and materials furnished to the company in conjunction with this application are hereby incorporated by reference into this application and made a part of this application.

Applicant Signature _____ **Title:** _____

(Must be signed by an owner, principal, partner or officer) **Date:** _____