



P.O. Box 650 • 57 Parker Rd. • Barre, VT 05641 • 800-548-4301 • www.neee.com

PHARMACEUTICALS SUPPLEMENTAL APPLICATION

COMPLETE IN ADDITION TO ACORD APPLICATIONS.

ATTACH ADDITIONAL SHEETS AS NECESSARY.

ANSWER ALL QUESTIONS. If not applicable, indicate N/A.

GENERAL INFORMATION

1)

Named Insured:			
Additional Named Insureds:			
Brokerage/Broker:			Agency/Agent:
Effective Date:			
Website:			

2)

Carrier:			
Limit of Insurance:			
Deductible:			Premium:
Policy Term Dates:			
Offering renewal? Yes <input type="checkbox"/> No <input type="checkbox"/>	Claims made? Yes <input type="checkbox"/> No <input type="checkbox"/>	Retroactive date:	

Please attach copies of the following:

- a) Currently valued five year loss runs, including claim detail for all losses open or exceeding \$15,000
- b) Your product brochure, catalog, or marketing materials if a website is not available
- c) A copy of your current financial statement, including balance sheet and income statement
- d) A copy of your expiring policy Declarations page for retroactive date and limits continuity

3)

Mailing Address: _____

City: _____ State: _____ Zip Code: _____

4)

Premise Address (if different from above): _____

City: _____ State: _____ Zip Code: _____

5)

Are you a(n): Corporation Individual Partnership LLC
 Joint Venture Other: _____

6)

Your enterprise is:
 For Profit Not for Profit Other: _____

7)

Audit/Inspection contact: _____

a. Phone number: _____

b. Email: _____

OPERATIONAL INFORMATION

8) What are your operations? _____

9) Please complete the below table regarding your sales:

Upcoming Year (est.):	Last 12 Months:	One Year Prior:	Two Years Prior:	Three Years Prior:

10) What percentage of your sales are outside of the United States? _____

11) Provide the following information for those products, goods and/or services you want coverage for. Only those products, goods and services listed below will be considered for coverage.

Products and Services	Applicant Acts as a(n)					No. of Years	% of Gross Receipts	Products and Goods sold to:					
	M	W	R	I	MR			M	W	R	C	O	

M: Manufacturer **W:** Wholesaler **R:** Retailer **I:** Importer **MR:** Manufacturer's Rep. **C:** Consumer Direct

O: Other (describe): _____

12) Are any new products to be introduced during the next year? Yes No
 a. If yes, please provide details: _____

13) Have you discontinued any products since last year? Yes No
 a. If yes, please provide details: _____

14) Do you directly import any products or raw materials? Yes No
 a. If yes, please attach a complete list of imported products or materials including the percentage of total sales, manufacturer, and country of origin.

15) Do you obtain Certificates of Insurance including coverage for Products Liability from each of your suppliers? Yes No
 a. Are you listed as an Additional Insured on these policies, or do you require proof of a blanket Additional Insured – Vendor endorsement? Yes No
 b. What minimum limits do you require? _____

16) Are all warning labels, instructions, and advertising material reviewed by outside counsel? Yes No

- 17) Do your products meet applicable government or industry standards? Yes No
- 18) Are you a member of any trade organizations? Yes No
 a. If yes, please list: _____
- 19) Do you comply with Good Manufacturing Practices (GMP)? Yes No
- 20) In the event that it becomes necessary to recall a product, do you have a recall plan in place? Yes No
 a. Do you have Product Recall insurance? Yes No
 b. What means would be used to secure the return and disposal of the product? _____

- 21) Have you ever had a product recall event? Yes No
 a. If yes, supply the following details: Date of recall(s): _____
 b. Voluntary? Ordered? By what agency? _____
 c. Product(s) involved: _____

 d. Reason for recall and how discovered: _____
 e. What was the remedy for the problem? _____
 f. What percentage of recalled goods were returned/repaired? _____
- 22) Are there any present situations that might give rise to an incident causing a product recall? Yes No
 If yes, please provide details: _____

PRODUCT INFORMATION

- 23) Do you formulate your products? Yes No
 a. If no, who formulates your products? _____
- 24) Are formulas reviewed, tested, and verified by an independent third party? Yes No
- 25) Do you offer any white labeling services (manufacturing of products which are then sold under another entity's brand name or label)? Yes No
 a. If yes, are all of your products sold white label? Yes No
- 26) Are any products sold under your brand name or label produced by another entity under a white label agreement? Yes No
 a. If yes, do you utilize the same company for all subcontracted manufacturing? Yes No
 b. Please list companies: _____
- 27) Are batch or product records, serial numbers or copies of guarantee/warranty cards maintained that would facilitate tracing whereabouts of products? Yes No
 a. If yes, confirm how long these records are maintained: _____
 b. Do these records include:
 + When and where the product was manufactured? Yes No
 + To whom the product was sold and the date of sale? Yes No
 + Who manufactured or supplied the product or ingredients? Yes No
 + Changes in formula/formulation notes? Yes No
 + Changes in advertising material/packaging notes? Yes No

28) Do you have a formal written internal quality control and testing program? Yes No
 a. If yes, confirm how long these records are maintained: _____

29) Do you manufacture, package, or repackage for direct to consumer distribution? Yes No
 a. If yes, do your labels meet FDA requirements for labeling? Yes No

30) Do any of your products require a Black Box warning? Yes No
 a. If yes, which product(s)? _____

31) Do you manufacture or distribute any Controlled Substances (as defined by the Controlled Substance Act) or any other product requiring DEA registration? Yes No
 a. If yes, which product(s)? _____
 b. License Number: _____

32) What percentage of your revenues is from products in the following categories? Check all that apply:

Ingredient	Percentage of Sales Last 12 Months	Estimated Percentage of Sales Next 12 months	Ingredient	Percentage of Sales Last 12 Months	Estimated Percentage of Sales Next 12 months
<input type="checkbox"/> Animal Use	%	%	<input type="checkbox"/> Birth Control	%	%
<input type="checkbox"/> Blood Products	%	%	<input type="checkbox"/> Controlled Substances	%	%
<input type="checkbox"/> Fertility Treatment	%	%	<input type="checkbox"/> Hormone Therapy	%	%
<input type="checkbox"/> Pediatric	%	%	<input type="checkbox"/> Selective Serotonin Reuptake Inhibitors (SSRIs)	%	%
<input type="checkbox"/> Topicals	%	%	<input type="checkbox"/> Vaccines	%	%

33) Please complete the following table for your product types:

Drug Type	Percentage of Products:
Over-the-Counter Medications	
Generic Prescriptions	
Brand Name Prescriptions	
TOTAL:	100%

34) Are any of your products currently being used in a clinical trial or any other tests involving human subjects? Yes No

a. If yes, please attach details about the trials, tests, or studies. ***If you are involved in the trials, tests, or studies and are seeking Professional Liability coverage for this exposure, please complete the Kinsale Allied Health Clinical Trials Supplemental Application.***

35) Do you promote your products for any off-label use? Yes No

a. If yes, please attach a description of the product(s), its approved use, the off-label use you are promoting, and supporting documentation of the acceptability of such off-label use.

COVERAGE AND LOSS HISTORY

- 36) Have you been inspected by the FDA in the last five years? Yes No
a. If yes, please list dates: _____

- b. Were you issued an FDA 483 form? *If yes, please attach copies as well as your response.* Yes No
- 37) Have you received any customer complaints in the last five years? Yes No
a. If yes, how many? _____
b. Please attach a description of product and complaint details, responses, investigations or testing, etc. in response to these complaints.
- 38) Have any adverse events concerning your products been reported to you or the FDA in the last five years? Yes No
a. If yes, how many? _____
b. Please attach a description of product and adverse event details, responses, investigations or testing, etc. in response to these events.
- 39) Have you been cited by any regulatory agency for violations arising out of business activity involving your product(s)? If yes, please provide details: Yes No

- 40) Have you had any Product Liability claims that were or were not covered by insurance? Yes No
If yes, please attach an explanation.
- 41) During the past five years, has any insurer ever canceled or non-renewed similar insurance to any applicant or has your insurance been canceled for nonpayment of premium by any insurance or finance company? **If yes, please attach an explanation.** Yes No
- 42) Is your company aware of any occurrences, facts, circumstances, incidents, situations, damages or accidents arising out of or related to your operations that a reasonably prudent person might expect to give rise to a claim or lawsuit whether valid or not which might directly or indirectly involve the company? **If yes, please attach an explanation.** Yes No

FRAUD WARNING

NOTICE TO ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, 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 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.

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 a 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 purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

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: _____ Title: _____

FEIN #: _____

Applicant's Signature: _____ Date: _____

Agent/Broker Name: _____