



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

LIFE SCIENCES PRODUCT RECALL 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:			
Brokerage/Broker:			Agency/Agent:
Renewal?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Policy Number:
Effective Date:			
Website:			

2)

Current Carrier Information:

Carrier:			
Recall Expense?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Recall Liability? Yes <input type="checkbox"/> No <input type="checkbox"/>
Cutoff Date:			
Deductible:			
Premium:			
Offering renewal?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

Please attach copies of the following:

- Currently valued five-year General Liability/Product Liability and Recall loss runs, and loss details for any recalls outside of coverage history. If you have had a recall, complete the Kinsale Product Recall Claim Supplement and include copies of all governmental agency documents for all recall claims and any applicable court documents
- Product brochure, catalog, or marketing materials if a website is not available
- Current policy declarations page for cutoff date (if applicable)
- Copy of your current recall plan, quality assurance/product testing protocols and methods, HACCP plan, SSOP/GMP plans, etc. as applicable to your operations

3)

Mailing address:

Address: _____

City: _____ State: _____ Zip Code: _____

4)

Premise address:

Address: _____

City: _____ State: _____ Zip Code: _____

- 5) Audit contact: _____
 a. Phone number: _____
 b. Email: _____
- 6) Years you have been in operation and selling products of the type for which you are seeking coverage: _____
- 7) Total sales of products for which coverage is being sought for the coming year: \$ _____
- 8) Projected number of units sold for which coverage is being sought for the coming year: _____

I. GENERAL INFORMATION

- 9) If you are seeking recall coverage for specific products only, please list them: _____

- 10) Have you ever had a product recall? **If yes, please complete and attach the Kinsale Recall Claim Supplement and copies of all pertinent government documents.** Yes No
- 11) Are any of your products presently under investigation, by yourself or any other entity or government authority, for a possible defect, flaw, contamination or other issue which may give rise to a product recall? If yes please attach details. Yes No
 a. Have you had any customer complaints about specific product(s)? If yes, attach details. Yes No
- 12) Do you carry General Liability (GL) or Products/Completed Operations (PRCO) liability insurance for your products? Yes No
- 13) Have you had any product liability claims within the last five years? Yes No
 a. If yes, how many? _____
 b. If you have had multiple claims, did they involve the same or very similar products? Yes No
 c. Has any product design changed as a result of claims? Yes No
- 14) What type of product are you selling? Check all that apply:
 Pharmaceuticals or Pharmaceutical Ingredients Nutraceuticals or Nutraceutical Ingredients
 Veterinary or Livestock Pharmaceuticals, Nutraceuticals or Pharmaceutical/Nutraceutical Ingredients
 FDA Class I Medical Devices Blood, Organs or Tissues – Human Use
 FDA Class II Medical Devices Blood, Organs or Tissues – Animal Use
 FDA Class III Medical Devices Cosmetics or Skincare Products or Ingredients
 Veterinary or Livestock Medical Devices or Medical Supplies
- 15) What is the nature of your sales? Check all that apply:
 Direct to consumer
 Business to Business – Complete/Packaged Goods for Sale
 Business to Business – Complete/Packaged Goods for Business Use
 Business to Business – Ingredients
- 16) How many products are in a normal batch or lot number? _____
- 17) In addition to your internal testing/quality control measures, are your products tested by any independent 3rd parties or government authorities? Yes No
 a. List testing agency or firm(s): _____
 b. How frequently is this testing done? _____

18) If you are not seeking coverage for a specific product(s) identified in 9) only, please complete the below for your top five products:

Product	Total sales	Average lot/batch size	Percentage of sales

- 19) Do you outsource any parts, components, or ingredients for your product? Yes No
- a. If yes, are any parts, components, or ingredients imported? Yes No
- b. If yes to a., what percent? ____%
- c. Do you track or maintain records of lot or batch numbers of sourced materials and the corresponding lot or batch of your products in which they have been incorporated? Yes No
- d. Have any of your suppliers ever notified you of a recall? Yes No
- e. Do any suppliers grant you indemnification for product recall? Yes No
- f. If yes to e., do you collect certificates of insurance (COIs) confirming AI status? Yes No
- 20) If you are selling business to business, do you provide any of your customers indemnification or hold harmless agreements relating to product recall? Yes No
- 21) How frequently are all processing, production, packing or other handling lines:
- a. Cleaned? _____
- b. Maintained/Mechanically Serviced? _____
- c. Shut down for deep sanitization? _____
- 22) Do you handle or process any common allergens (nuts, dairy, soy, etc.) in any of your facilities? Yes No
- a. If yes, does your labeling notify of possible contamination?
- b. Do you source from suppliers who may reasonably be assumed to handle common allergens? Yes No
- 23) Are your products subject to any government agency or authority labeling regulations? Yes No
- 24) Please check the federal agencies' rules and authority under which your products are subject to regulation:
- Food and Drug Administration (FDA) United States Department of Agriculture (USDA)
- Consumer Product Safety Commission (CPSC) Center for Biologics Evaluation and Research (CBER)
- Other: _____ Center for Devices and Radiological Health (CDRH)
- 25) What is the shelf life of your products? _____
- a. If your product is an ingredient/additive of another company's product, does the final product have the same shelf life as your product? If no, please clarify: _____
- 26) Have you ever been subject to a criminal tampering/intentional adulteration incident? Yes No
- If yes, please attach details and a copy of any applicable police reports.
- 27) Have you ever received a violation notice from the FDA or other similar agency that did not result in a recall? If yes, please attach a copy as well as any follow up reports, re-inspections, and the corrective action plan implemented. Yes No

II. PHARMACEUTICAL/NUTRACEUTICAL *(skip this portion if you do not sell pharmaceutical/nutraceutical goods)*

- 28) Do you do your own research and development or formulation? Yes No
a. If no, are formulations provided to you by your client or customer? Yes No
b. Please describe the qualifications of and any professional designations held by the person or persons responsible for product formulation: _____

- 29) Do you track reported adverse effects or other customer complaints? Yes No
a. If yes, how long are these records retained? _____
b. Are incidents always reported to the FDA Adverse Event Reporting System (FAERS)? Yes No
- 30) Do you sell biosimilars of FDA approved products which are not themselves approved? Yes No
- 31) Are any of your products frequently prescribed for off-label use for which they are not approved? Yes No
a. If yes, please clarify: _____
- 32) Are any of your products considered homeopathic, ayurvedic or otherwise alternative medicine in nature? Yes No
- 33) Have any of your products ever been permanently removed from the market or banned from sale? If yes, please list: _____
- 34) Do you sell any cannabis products? Yes No
a. Are products cannabidiol (CBD) only, compliant to United States H.R.2 - Agriculture Improvement Act of 2018, Title X, Subtitle G – Hemp Production? Yes No
b. Are all products tested for concentration and contamination by an independent 3rd party or state assigned laboratory? If yes, please attach a copy of your last testing results. Yes No
c. Are product labels reviewed by legal counsel? Yes No
d. Do any product labels speak to medical conditions or intended therapeutic usage? Yes No

III. BLOOD, ORGANS AND TISSUES *(skip this portion if you do not sell blood, organs or tissues)*

- 35) Do you have dedicated staff monitoring CBER updates to biologics guidance? Yes No
a. Please attach a copy of your screening questionnaire and guidelines as applicable.
b. How frequently are your donor guidelines and screening procedures updated? _____
- 36) Have you or any of your suppliers ever been subject to increased FDA inspection of your facilities? Yes No
a. If yes, please attach additional information and a copy of your corrective action plan.
- 37) Do you sell cadaver organs or tissues? Yes No
- 38) Do you sell living donor organs or tissues? Yes No
- 39) Do you sell blood, organs or tissues for laboratory use only? Yes No

IV. MEDICAL DEVICES *(skip this portion if you do not sell medical devices)*

- 40) Do you sell any medical devices outside of the US which are banned or have otherwise been removed from the market by the FDA (prosthetic hair fibers, polypropylene breast implants, powdered surgical gloves, etc.)? Yes No
a. If yes, what? _____

- 41) Do you participate in the FDA Voluntary Malfunction Summary Reporting Program? Yes No
- 42) Have you ever had an FDA form 3500A mandatory reporting event? Yes No
 a. If yes, has the device involved had any subsequent failures of malfunctions of a similar type in another patient or patients? Yes No
 b. If yes, please attach details.
- 43) Are any of your products possibly subject to cybersecurity vulnerabilities (hacking or other unauthorized access, electromagnetic pulse sensitivity, programming errors)? Yes No
 a. If yes, how frequently are devices tested for emerging cyber threats? _____
 b. How are healthcare providers and patients alerted to firmware updates and vulnerabilities? _____

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: _____