



www.CoverX.com

SEND SUBMISSIONS TO:

MASSACHUSETTS
lifescience@coverx.com

Producer: _____

Producer Is: Wholesaler Retailer

Address: _____

Telephone: _____

Fax: _____

Excess & Surplus Lines License No.: _____

Email: _____

Proposed Effective Date: _____

If Renewal, Provide Current Policy No.: _____

LIFE SCIENCE LIABILITY APPLICATION

INSTRUCTIONS: Please answer the following questions to provide us with the information necessary to properly evaluate your Life Science insurance exposures.
(Spaces will expand as you type.)

- Answer all questions completely, leaving no blanks. If any questions, or portions of a question do not apply, print "N/A" in the space.
- If you need more space to provide additional information and/or supporting attachments, attach a separate sheet and reference the question number.
- This application must be signed and dated by an officer of the company.

PLEASE ATTACH THE FOLLOWING:

- Current product listing
- Financial statements for private entity, or for a public entity that has not yet filed an SEC Form 10-K
- Five years of insurance carrier loss runs
- Active clinical trial schedule for upcoming policy term (include product name/protocol number, number of new enrollees, number of placebos, indication, trial phase, and country)
- Copies of Protocols and Informed Consent Template for active or planned trials for the next 12 months.

GENERAL INFORMATION

1. Name of Insured (as it should appear on the Policy):	
2. Additional Named Insureds (as they should appear in the policy):	
3. Are you a Corporation, Partnership, LLC, Joint Venture, Individual, Other?	
4. Mailing Address (as it should appear on the Policy):	
5. Website Address:	
6. Contact Name, Telephone Number, and Email Address:	
7. Coverage(s) and Limit(s) requested:	
8. Current Insurance Program structure. Please outline limits, deductible/SIR, aggregate retention, policy effective and expiration dates, retroactive dates and premium.	

<p>9. How many years have you been in business under your present name?</p>	
<p>10. Projected Sales (for the upcoming policy term):</p> <ol style="list-style-type: none"> United States Canada UK, Ireland and Australia Rest of the World 	
<p>11. General Description of Operations. Please include a description of your major product lines or services, whether you manufacture or distribute others' products, etc.</p>	
<p>12. Which of the following best describes your organization? Please indicate the percentage of revenue applicable to each segment.</p> <ol style="list-style-type: none"> Biotech/Pharmaceutical Contract manufacturing Contract research Dietary Supplement Medical Device Other 	
<p>13. Have you acquired any companies in the last three years in which you have 50% or greater ownership interest? If yes, did you acquire the liabilities?</p>	
<p>14. What percentage of your revenues are generated from license agreements, cooperation or collaboration agreements and royalties? If the percentage is greater than 25%, please provide copies of the 2 largest agreements in terms of revenue generated.</p>	
<p>15. Please estimate the annual number of users of your products. How many total users to date?</p>	
<p>16. Have any of your products been on the market for less than 3 years? If yes, please describe them, and if applicable, please list those that include new active pharmaceutical ingredients.</p>	
<p>17. Do you have any past, present or planned association with any products that are known teratogens, mutagens or carcinogens? If yes, please explain.</p>	
<p>18. Please describe your use of nanotechnology.</p>	
<p>19. If you would like us to consider providing coverage for your exposure to any of the following, please identify the extent of your exposure and your loss prevention controls:</p> <ul style="list-style-type: none"> • Selective Serotonin Reuptake Inhibitors (SSRI) • Isotretinoin (sometimes also spelled Isotrentinoin) • Thalidomide • Phentermine used in combination with Fenfluramine (including, but not limited to, Pondimin) or Dexfenfluramine (Redux) • Ephedra, Ephedrine or Pseudoephedrine, except where used in Prescription products • Vaccines approved for persons under eighteen (18) years of age • Live virus vaccines • Animal derived products • Any good or product containing Mercury where such good or product is or is intended to be implanted, ingested, injected, inhaled, or absorbed • Hormone replacement products approved for menopause treatment or which is intended to be used for such treatment • Any good or product containing liquid or gel Silicone which is intended to be implanted • Latex gloves • Di-(2-ethylhexyl) Phthalate (DEHP) used in goods or products approved for neonatal patients • Birth control or fertility goods or products 	

CLINICAL TRIALS INFORMATION – If N/A, indicate here:

20. Are you conducting any clinical trials? If yes, please attach trial protocols and informed consent documents for active trials. If there are no active Phase I trials, please supply a sample trial protocol and informed consent document for any active trial.	
21. Please advise if you are planning on phase one clinical trials in the next twelve months. If yes, please attach latest draft protocols and informed consent.	
22. How many human clinical trial participants do you plan to enroll during the upcoming policy term? How many potential participants will be screened? How many of the participants will receive placebos?	
23. Please provide the total number of human clinical trial participants enrolled in the last 3 years.	
24. Have any of your clinical trials been approved by an IRB or Ethics Committee that were previously rejected by a different IRB or Ethics Committee? If yes, please explain.	
25. Please provide data per year for each of the last 5 years: a. Total medical expenses incurred to treat participants for adverse events that occurred during your clinical trials. b. The number of participants receiving treatment. c. Total enrolled participants for each year. d. The largest single medical expense each year.	
26. Have any clinical trials with which you have been associated been discontinued, suspended, or placed on regulatory hold due to safety reasons in the last 3 years? If yes, please provide details.	
27. Have any of your Clinical Investigators been cited for regulatory violations associated with clinical trials? If yes, please provide details.	
28. Are you aware of any serious regulatory non-compliance or fraud by Clinical Investigators and/or their staff in the past 3 years involving your trials? If yes, please provide details.	

While not required, responding to questions 29-34 below may enable us to provide more favorable terms, conditions and pricing.

29. Do you require all informed consent documents to be readable at an 8 th grade level or below? If not, please explain your reasons.	
30. Please describe any formalized policies for expanded access or compassionate use.	
31. Have you published all your clinical studies? If not, please explain.	
32. How do you ensure compliance with the applicable local, state, provincial, regional and federal laws and IRB or Ethics Committee requirements regarding human clinical trials?	
33. How do you determine if there may be a conflict of interest with any Clinical Investigators or employees? Do you incorporate financial disclosures in your informed consent documents and processes?	
34. Please describe your process for selecting your Clinical Investigators? How do you audit your Clinical Investigators? Please describe your training and monitoring process for Clinical Investigators.	

REGULATORY/SAFETY SURVEILLANCE INFORMATION

35. Have you received any warning letters from or have you been cited for any GMP, GLP, GCP, OS, or Advertising & Promotion violations by the FDA, FTC, or any equivalent governmental authority in the last 3 years? If yes, please provide details.	
36. Do you have any outstanding compliance issues with the FDA or any equivalent regulatory agency? If yes, please provide details.	
37. Other than the FDA or FTC, have you been investigated or cited by a regulatory or governing body for violation of or non-compliance with any local, state, provincial, regional, or federal law in the last 5 years? If yes, please explain.	

38. Have any of your directors, officers, partners, or members been investigated for alleged criminal violations relating to your business in the last 5 years? If yes, please explain.	
39. Has your product, any product containing your product, or any product on which your work was performed been banned, seized, or discontinued for safety reasons by the FDA or any equivalent regulatory agency or government entity? If yes, please provide details.	
40. How many product recalls have you had in the last 5 years? How many were Class I recalls?	
41. Have you added a black box warning to or updated any black box warning of your products in the last 5 years? If yes, please explain.	
42. Have you made any changes in product design, formulation, or specifications as the result of data or information from adverse events or your safety surveillance activities in the last 5 years? If so, please explain.	
43. Please identify any safety surveillance team or member recommendations requiring remedial actions that have yet to be implemented (e.g. additional studies, black box warning label, "Dear Healthcare Professional" letter, expanded product monitoring, product recall/withdrawal, etc.	
44. List your top three products in terms of number of Adverse Event Reports where the product was associated with death, permanent injury or hospitalization. Please provide a copy of the most recent Periodic Safety Report for these products.	

While not required, responding to questions 45-49 below may enable us to provide more favorable terms, conditions and pricing.

45. Who are the members of your safety surveillance team and to whom does the team report?	
46. Does your safety surveillance team have contact with and/or report to your outside board of directors?	
47. Who has the authority to suspend a trial, approve a label change, or withdraw a product from the marketplace? Do you have written procedures to address and communicate these actions?	
48. Under what circumstances do you use independent parties to analyze your processes or data?	
49. What steps, if any, would you take if you became aware of a pervasive off-label use of your products?	

PREMISES INFORMATION

50. Please describe the amount of hazardous substances you have at each of your locations.	
51. What is your highest biosafety level rating? Please list the addresses of all labs with this rating.	
52. Have you ever had a physical security breach of any premises you occupy? If yes, please provide details.	
53. Have you ever had a biohazard release? If yes, please provide details.	

While not required, responding to questions 54-55 below may enable us to provide more favorable terms, conditions and pricing.

54. If applicable, how do you control hazardous substances at your premises?	
55. If applicable, are you in compliance with local, state, provincial, regional and federal laws regarding hazardous materials handling and disposal? If not, please explain.	

While Not Required, Responding To The Risk Management, Sales & Marketing Information Sections Below May Enable Us To Provide More Favorable Terms, Conditions And Pricing.

RISK MANAGEMENT INFORMATION

56. Are your operating policies and procedures audited annually? Provide an overview of your audit procedures. To whom does the audit team report? Who receives a copy of the audit report?	
57. Do you have a Compliance Officer? If yes, to whom does the officer report?	
58. Do you have an Enterprise Risk Management program? If yes, please describe it.	
59. Please describe your quality control procedures regarding the use of imported ingredients, components, or products.	
60. Do any of your employees have direct patient contact? If yes, please provide details.	
61. Do you follow the PhRMA Code or similar organization guidelines as respects interactions with Healthcare Professionals?	
62. Please describe how you monitor your contractual obligations for confidentiality agreements and granting of additional insured status.	
63. Please describe your claims escalation procedures.	
64. Do you have formalized information privacy policies and procedures that are in compliance with applicable local, state, provincial, regional, and federal laws?	
65. Do you have a code of conduct and annual training/certification for employees? Do you have a system for documenting compliance violations and corrective actions?	
66. Do you have a hotline to allow employees to report concerns about potential violations? If yes, does it allow for anonymous reporting?	
67. How do you communicate that new employees should not bring intellectual or personal property with them from former employers?	
68. Please describe or detail any information which you feel has not been asked that would help us to better evaluate your company.	

SALES & MARKETING INFORMATION – If N/A, indicate here:

69. Please describe the extent of your direct to consumer advertising. How do you ensure your advertisements to consumers are both balanced and informative?	
70. Under what circumstances does someone other than a senior officer or an attorney in your legal department have the authority to sign contracts?	
71. Are all contract changes required to be in writing and signed by both parties?	
72. How do you ensure that your internal and external sales and marketing representatives inform customers about product warnings, contraindications, labeling, and use?	
73. Do you allow any off-label information dissemination by sales representatives? Do other employees provide off-label information? If yes, what is your system for managing and documenting these activities?	
74. Do you allow employees to advertise direct product comparisons against competitors' products? If yes, which employees are authorized to make these comparisons? How do you ensure competitors' products are not disparaged?	
75. How often do you train your sales and marketing staff on products' liability exposures?	
76. If you had evidence that your internal and/or external sales and marketing staff was not in compliance with local, state, provincial, regional, or federal laws, how would you handle it?	
77. To what extent is your marketing group involved with scientific educational programs? Is your grant-giving function independent of your sales and marketing department?	

HISTORICAL AND LOSS INFORMATION

78. Has any insurance company cancelled, rescinded, or refused to renew your insurance coverage for Products or General Liability? If yes, please explain.	
79. Have any of your products or services ever been involved in class action or multi-district litigation? If yes, please provide details.	
80. How many times in the last 5 years has a claim or demand for damages exceeded your deductible or retention? Please provide details.	
81. Are you aware of any fact, circumstance, or situation which one might reasonably expect to give rise to a claim that would fall within the scope of the insurance being requested? Any claim or demand for damages not yet reported? If yes, please provide details.	

DECLARATIONS

I declare that the statements and particulars in this application are true and that no material facts have been misstated or suppressed after enquiry. I agree that this application, together with any other information supplied shall form the basis of any contract of insurance effected thereon. I undertake to inform the Insurers of any material alteration to those facts occurring before completion of the contract of insurance. A material fact is one which would influence the acceptance or assessment of the risk.

I certify that I have read and understand the applicable fraud warning set forth below:

ANY PERSON WHO KNOWINGLY AND WITH INTENT TO DEFRAUD ANY INSURANCE COMPANY OR ANOTHER 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 THE PERSON TO CRIMINAL AND [NY: SUBSTANTIAL] CIVIL PENALTIES. (Not applicable in CO, DC, FL, HI, MA, MD, NE, OH, OK, OR, VT or WA- see Additional Fraud Notices attached hereto for these States). INSURANCE BENEFITS MAY ALSO BE DENIED.

Signature: _____

Date: _____

Position: _____

ADDITIONAL FRAUD NOTICES

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 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.

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 INSURER FILES A STATEMENT OF CLAIM OR AN APPLICATION CONTAINING ANY FALSE, INCOMPLETE OR MISLEADING INFORMATION IS GUILTY OF A FELONY IN 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 MARYLAND APPLICANTS: 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.

NOTICE TO MASSACHUSETTS, NEBRASKA, OREGON AND VERMONT APPLICANTS: ANY PERSON WHO KNOWINGLY AND WITH INTENT TO DEFRAUD ANY INSURANCE COMPANY OR ANOTHER 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, MAY BE COMMITTING A FRAUDULENT INSURANCE ACT, WHICH MAY BE A CRIME AND MAY SUBJECT THE PERSON TO CRIMINAL AND CIVIL PENALTIES.

NOTICE TO OHIO APPLICANTS: 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.

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 WASHINGTON 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.