

## Berkley Life Sciences Excess Application

**NOTICE: THIS IS AN APPLICATION FOR A CLAIMS MADE & REPORTED POLICY UNLESS OTHERWISE PROVIDED. THE LIMIT OF LIABILITY TO PAY DAMAGES OR SETTLEMENTS WILL BE REDUCED AND MAY BE EXHAUSTED, UNLESS OTHERWISE PROVIDED HEREIN, BY "DEFENSE COSTS", AND "DEFENSE COSTS" WILL BE APPLIED AGAINST THE DEDUCTIBLE AMOUNT. SHOULD THIS APPLICATION BE ACCEPTED BY THE COMPANY, THE POLICY WILL NOT APPLY TO CLAIMS FIRST MADE AND REPORTED AGAINST THE INSURED AFTER THE END OF THE POLICY PERIOD (UNLESS THE EXTENDED REPORTING PERIOD APPLIES) OR CLAIMS FIRST MADE PRIOR TO THE RETROACTIVE DATE SHOWN IN THE DECLARATIONS PAGE.**

**THE COMPLETION AND SUBMISSION OF THIS APPLICATION TO THE COMPANY DOES NOT CONSTITUTE A BINDER OF INSURANCE UNDER ANY CIRCUMSTANCES. ALL QUESTIONS MUST BE ANSWERED. IF A QUESTION OR SECTION IS NOT APPLICABLE, PLEASE ANSWER "NA". IF THE ANSWER TO A QUESTION IS NONE, STATE "NONE" OR "0". IF MORE SPACE IS REQUIRED TO ANSWER A QUESTION COMPLETELY, PLEASE PROVIDE A SEPARATE ATTACHMENT AND IDENTIFY THE QUESTION IT RESPONDS TO.**

**THE APPLICATION IS A WORD DOCUMENT. BY SIGNING THIS DOCUMENT, THE UNDERSIGNED AGREES THAT NO QUESTIONS HAVE BEEN MODIFIED OR CHANGED.**

*In completing this application, if the information requested was provided in the underlying application, note the specific reference point in the underlying application where the information can be located.*

<p><b>1. Have any of your products been in the marketplace for less than 5 years?</b></p> <p>If yes, please list products.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>2. Have you had any company product(s) banned by the FDA or equivalent regulatory agency, or were discontinued for safety reasons?</b></p> <p>If yes, please provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>3. How many product recalls have you had in the past 5 years?</b></p> <p>Describe in detail any Class 1 recalls?</p>	<p>0 Please select</p>
<p><b>4. Have you had any company product(s) that required the addition of a black box warning to existing labeling in the last 5 years?</b></p> <p>If yes, please describe the products.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>5. Have you had any company product(s) where these product(s) were the cause of adverse events that resulted in a death, permanent injury, or hospitalization in the last 3 years?</b></p> <p>If yes, please list the products.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

<p><b>6. Where applicable, identify any safety surveillance team recommendations requiring remedial actions that have yet to be implemented or completed. Examples include:</b></p> <p> <input type="checkbox"/> Additional Studies                      <input type="checkbox"/> Expanded Product Monitoring  <input type="checkbox"/> Black Box Warning Label              <input type="checkbox"/> Product Recall / Withdrawal  <input type="checkbox"/> "Dear Healthcare Professional" Letter    <input type="checkbox"/> N/A </p> <p>If any box, other than N/A is checked, please explain:</p>	
<p><b>7. Have you had any company product(s) that have been submitted to a FDA Advisory Committee in the last 5 years where non- approval was recommended, or if recommended for approval received less than a 2/3 majority committee approval vote?</b></p> <p>If yes, please list the products and provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>8. Have any company manufacturing operations been suspended by a regulatory agency in the last 3 years?</b></p> <p>If yes, please provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>9. Has the company received any warning letters from the FDA or FTC or equivalent regulatory agency in the last 5 years?</b></p> <p>If yes, please list the products and provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>11. Has the company been subject to a criminal investigation in the last 5 years?</b></p> <p>If yes, please list the products and provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p><b>12. Have any clinical trials in which you have been associated with been discontinued or suspended due to safety reasons in the last 5 years?</b></p> <p>If yes, please provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
<p><b>13. Have any of the Clinical Investigator's the company has been associated with been cited for regulatory violations involving your trial activities?</b></p> <p>If yes, please list the products and provide details.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>

<p><b>14. Has the company had any evidence of serious regulatory non-compliance or fraud by Clinical Investigator's and their staff in the past 5 years involving your trials?</b></p> <p>If yes, please provide details</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>15. Does the applicant have any reason to expect that any of the events listed in 1-14 above will occur during the upcoming policy term?</b></p> <p>If yes, please provide details.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>16. Does the company have any outstanding compliance issues with the FDA or equivalent regulatory agency?</b></p> <p>If yes, please provide details.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>17. Have you at any time in the last 12 months: (a) contemplated, or are you currently contemplating or in the process of implementing, any actual or potential reorganization or liquidation, or any arrangement with creditors under federal or state law; or (b) been delinquent on debts, loans, guarantees or financial obligations for more than 30 days, where the total amount of such delinquency in the last 12 months is in excess of \$25,000?</b></p> <p>If yes, please provide details.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>18. Any demand for damages not yet reported?</b></p> <p>If yes, please provide details.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>19. Have you had any product or service past or present that, is or has been, involved with class action or multi-district litigation?</b></p> <p>If yes, please list the product or service.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>20. Is the applicant aware of any multi-district, multi-claimant, or class action involving any product on the market that is in the same class as any product the applicant sells or has sold?</b></p>	

<p><b>21. Is the applicant aware of any fact, circumstance, or situation which one might reasonably expect could give rise to a claim that would fall within the scope of the insurance being requested?</b></p> <p>If yes, please provide details.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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**NOTICE TO APPLICANT - PLEASE READ CAREFULLY.**

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, INCLUDING BUT NOT LIMITED TO FINES, DENIAL OF INSURANCE BENEFITS, CIVIL DAMAGES, CRIMINAL PROSECUTION AND CONFINEMENT IN STATE PRISON.

The Applicant's submission of this Application does not obligate the Company to issue, or the Applicant to purchase, a policy. The Applicant hereby authorizes the Company to make any inquiry in connection with this Application. The information requested in this Application is for underwriting purposes only and does not constitute notice to the Company under any policy of a Claim or potential Claim

**COMPLETION OF THIS APPLICATION DOES NOT BIND COVERAGE. APPLICANT'S ACCEPTANCE OF THE COMPANY'S QUOTATION IS REQUIRED PRIOR TO BINDING COVERAGE AND POLICY ISSUANCE**

**IF THE ANSWERS IN THIS APPLICATION CHANGE MATERIALLY BEFORE THE POLICY INCEPTION DATE, THE APPLICANT MUST IMMEDIATELY NOTIFY THE COMPANY IN WRITING, AND ANY OUTSTANDING QUOTATION MAY BE MODIFIED OR WITHDRAWN.**

The undersigned authorized officer and agents of the applicant declares to the best of their knowledge and belief, after reasonable inquiry, the statements made in this application and in any attachments or other documents submitted with this Application are true and complete. The undersigned knows of no other relevant facts which might affect the Company's judgment when considering this application and represents that the statements herein are true, accurate, and complete. The undersigned agree that this Application and such attachments and other documents shall be the basis of the insurance policy should a policy providing requested coverage be issued, and the Company will have relied on all such materials in issuing any such policy.

Authorized Signature of Applicant	Title	Date
Print Name	Email Address	
Applicant/Company Name	FEIN/Federal Tax Identification Number	
Address (No, Street, City, State and Zip Code)		
Submit By Agent/Broker (Signature)	Title	Date
Address (No, Street, City, State and Zip Code)	Agent/Broker Surplus License No. (a copy of valid surplus lines license will be required.)	

**\*PLEASE INCLUDE THE FOLLOWING WITH THIS APPLICATION:**

1. Underlying Carrier's completed Life Science Application, Submission, Quote/Binder, Applicable Policy Specimen & Endorsements
2. If private, most recent financial statement