# Renewal Application for The Hartford Life Sciences Elite℠

**Notice: claims made and defense within limits**

The liability coverage parts under the policy provide coverage on a "claims made" and "defense within limits" basis. Except as may be otherwise specified in the policy or endorsements: your coverage will apply only to a covered cause of loss that takes place between the retroactive date and the end of the policy period. In addition, coverage will apply only to claims first made against the insured to us after the inception date and before the end of the policy period or any applicable extended reporting period.

The limits of insurance under the policy will be reduced and may be exhausted by payment of any combination of damages, defense costs and supplementary payments. When we have paid our limits of insurance, our right and duty to defend any insured against a claim or suit ends. Coverage is subject to the insured's payment of any applicable retention.

**Please attach:**

- A list of any additional named insureds with a description of operations for each;
- A list of retroactive dates to be applied to coverages, limits, or entities;
- If you're a private company, please attach a copy of your most recent audited financial statements; and
- An active clinical trial schedule for the requested policy term. Include product name/protocol and attach a sample copy of informed consent for an active trial.

## A. General Information

| | |
|---|---|
| Name of Insured (as it should appear on the policy): | |
| Mailing Address: | |
| Website URL: | |
| Parent Company (if any): | |
| Prior Company Names (if any): | |
| Have there been asset or entity acquisitions in the last three years? If yes, please describe: | |
| Projected annual unique users in the next year: | |

| B. Exposure Basis (Please provide projected gross and net sales if applicable.) | | C. Exposure Basis (Please provide active clinical trial participant counts for upcoming policy period if applicable.) | |
|---|---|---|---|
| United States | | United States | |
| Canada | | Canada | |
| United Kingdom & Ireland | | United Kingdom & Ireland | |
| Europe (EU) | | Europe (EU) | |
| Australia | | Australia | |
| Southeast Asia | | Southeast Asia | |
| Rest of the world | | Rest of the world | |
| Intercompany | | Number of enrollees noted above receiving placebo | |
| Pass-through and Royalty Payments | | Total number of participants enrolled in your trials the last three years | |

## D. Exposure Basis (Please provide the medical professionals if applicable.)

| Health Professionals | Specialty | Hours of Direct Patient Care | # of Applicant Employees | # of Independent Contractors |
|---|---|---|---|---|
| Physicians | | | | |
| RNs | | | | |
| LPNs | | | | |
| Pharmacists | | | | |
| Medical Technicians | | | | |
| EMTs | | | | |
| Other: (please describe) | | | | |

Details:

## E. Liability Coverage Requested

| | Overall Policy Aggregate Limit ($1M - $15M) | Overall Policy Retention Aggregate (None or 1x - 5x) |
|---|---|---|
| Amounts requested to be over all the coverages selected below | | |
| **Coverage** | **Limits Requested** | **Retention (DED/SIR) Requested** |
| Products & Completed Operations ($1M to $15M)* | | |
| Professional Services Liability for bodily injury & property damage ($1M to $15M)* | | |
| Sublimited Coverages for Products & Completed Operations and Professional Services Liability: | | |
| • Product Withdrawal Expense ($50K to $1M available) | | |
| • Product Shortage Liability ($50K to $1M available) | | |
| • Medical Monitoring Liability ($50K to $1M available) | | |
| • Property in your care, custody or control ($1M to $15M available) | | |
| Do you want any of the above coverages basketed? ☐ Yes ☐ No | | |
| If yes, what's the amount of the basket requested? (A $250K basket is automatically provided.) | | |
| Human Clinical Trials Liability for bodily injury & property damage ($1M to $15M) | | |
| Sublimited Coverages for Human Clinical Trials Liability: | | |
| • Clinical Trial Sexual Abuse & Molestation Liability ($100K to $1M available) | | |
| • Denial of Access, including Right to Try ($50K to $1M available) | | |
| • No-fault clinical trial coverage ($50K to $250K available) | | |
| • Human Clinical Trial Medical Monitoring Liability ($50K to $1M available) | | |

| | | |
|---|---|---|
| Do you want any of the above coverages basketed?<br>Yes No<br>If yes, what's the amount of the basket requested? (A $250K basket is automatically provided.)<br>• Research Health Coverage/Medical Expense ($10K to $250K available) | | |
| Errors & Omissions Liability (financial damages only) ($1M to $10M available) | | |
| Sublimited Coverages for Errors & Omissions Liability:<br>• Product Withdrawal Liability - financial damages only ($1M to $10M available)<br>• Performance Delay ($1M to $5M available) | | |
| Cyber Coverages ($1M to $2M available)<br>• Cyber Liability Coverages<br>» Privacy Liability (including Privacy Regulation Proceedings & Fines and PCI Fines & Assessments)<br>» Cyber Security Liability<br>• Privacy Breach Response and Crisis Management Coverages<br>» Privacy Breach Response<br>» Crisis Management | Cyber Aggregate limit: $1M to $2M available<br>Liability coverage limits: Must match overall Cyber Aggregate limit<br>Privacy Breach limit: Must be equal to or less than the Cyber Aggregate Limit | |
| Pollution Liability Coverages | Only $1M limits available for each | Only $5,000 retention available |
| • Contractors Pollution Liability | Requested: Yes No | |
| • Transportation Pollution Liability | Requested: Yes No | |
| • Waste Disposal Facilities/Third-party Storage Facilities | Requested: Yes No | |
| • Pollution Liability for Your Site | Requested: Yes No | |
| Details: | | |

* Products and Completed Operations and Professional Services Liability fall under the same limit when both coverages are chosen.

## F. Open Exposure Items

| | | |
|---|---|---|
| 1. Do you have any products in your portfolio that are currently the subject of litigation? | Yes | No |
| 2. Do you have any open safety surveillance team or member recommendations requiring remedial actions that have yet to be implemented? | Yes | No |
| 3. Have you at any time in the last 12 months:<br>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<br>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? | Yes | No |

| | | |
|---|---|---|
| 4. In the last 12 months, regarding your product, or any product incorporating your product or on which your work was performed, have there been any:<br>a. Regulatory warning letters; c. Black box label modifications/additions; or<br>b. Class 1 Product recalls; d. Suspensions of a clinical trial for safety reasons<br>If yes, explain in detail: | ☐ Yes | ☐ No |
| 5. Do you have any reason to expect that any of the events listed in a–d above will occur during the upcoming policy term? If yes, explain in detail: | ☐ Yes | ☐ No |
| 6. Are you aware of: | | |
| a. 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? | ☐ Yes | ☐ No |
| b. Any claim or demand for damages not yet reported to any prior or current insurance carrier? | ☐ Yes | ☐ No |
| c. Any claim that has become part of multi-district litigation, multi-claimant litigation, or part of a class action? | ☐ Yes | ☐ No |
| d. Any multi-district litigation, multi-claimant litigation or class action involving any product on the market that contains the same ingredient as is contained in your product, or is in the same device family as your product, or in which your product was incorporated or on which you performed a service? If yes, explain in detail: | ☐ Yes | ☐ No |
| 7. Have you received any warning letters from, or have you been cited for any GMP, GLP, GCP, QS, or Advertising & Promotion violations by the FDA, FTC, or any equivalent governmental authority in the last year? If yes, provide details and describe any outstanding compliance issues: | ☐ Yes | ☐ No |
| 8. 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 year? If yes, explain: | ☐ Yes | ☐ No |
| 9. Have any of your directors, officers, partners or members been investigated for alleged criminal violations relating to your business in the last year? If yes, explain: | ☐ Yes | ☐ No |
| 10. 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?<br>If yes, provide details: | ☐ Yes | ☐ No |
| 11. Are any of your products, clinical trials, or services specifically excluded on your existing policy?<br>If yes, provide details: | ☐ Yes | ☐ No |
| 12. Are you aware of any serious regulatory non-compliance or fraud by Clinical Investigators and/or their staff in the past year involving your trials?<br>If yes, provide details: | ☐ Yes | ☐ No |

| | | |
|---|---|---|
| 13. Do you have any past, present, or planned exposure to products that don't have formal FDA approval for marketing?<br>If yes, describe: | Yes | No |

## G. Newly Anticipated Exposures

| Do you have any planned or anticipated exposure to any of the following: | | |
|---|---|---|
| 1. Birth control or fertility goods or products | Yes | No |
| 2. Bisphosphonates | Yes | No |
| 3. Cold therapy product, meaning any device that operates by pumping liquid through a plastic bag or other receptacle and is applied to the body to reduce temperature | Yes | No |
| 4. Diethylstilbestrol (DES) | Yes | No |
| 5. Ephedra, Ephedrine or pseudoephedrine except where used in prescription products | Yes | No |
| 6. Hormone replacement products approved for menopause treatment, or which is intended to be used for such treatment | Yes | No |
| 7. Isotretinoin | Yes | No |
| 8. Live virus vaccines | Yes | No |
| 9. Mercury product, meaning any good or product containing mercury where such good or product is or is intended to be implanted, ingested, injected, inhaled or absorbed | Yes | No |
| 10. Mesh implants, meaning surgical mesh or other similar product or woven fabric either temporarily or permanently implanted into a human | Yes | No |
| 11. Metal-on-metal implant meaning any knee, hip or other joint implant, replacement or resurfacing system and the component parts of any of the foregoing ("implant") where: (1) a part of the implant designed for motion is made of metal; and (2) the moving part, while either at rest or in motion, contacts another metal part of the implant that's designed for motion, or designed to meet or serve as a socket or contact surface against which the moving part comes to rest | Yes | No |
| 12. Metoclopramide | Yes | No |
| 13. Opioids | Yes | No |
| 14. Pain pumps, meaning any infusion pump or other device where a part of the device or a line or tube connected to the device is inserted or implanted into the body to deliver pain medication directly to a joint, tissue or other specific internal body part or area of the body | Yes | No |
| 15. Phentermine used in combination with flenfluramine (including but not limited to Pondimin) or dexfenfluramine (Redux) | Yes | No |
| 16. Phospho soda, sodium phosphate, or any phospho soda or sodium phosphate based agents | Yes | No |
| 17. Rosiglitazone | Yes | No |
| 18. Selective Serotonin Reuptake Inhibitors (SSRI) | Yes | No |
| 19. Silicone product (implanted), meaning any good or product containing liquid or gel silicone which is intended to be or which is implanted | Yes | No |
| 20. Testosterone replacement products approved for testosterone deficiency treatment, or which is intended to be used for such treatment | Yes | No |
| 21. Thalidomide | Yes | No |
| 22. Vaccines approved for persons under eighteen (18) years of age during the policy period for which you are applying for coverage? | Yes | No |

## H. Warranty, Authorized Signature and Continuing Duty to Update

The person signing the application is authorized to make the above representations on behalf of the applicant, and a representation that the information is accurate. Signing this application does not bind coverage. The applicant's acceptance of the company's quotation is required before insurance coverage is bound and a policy issued. The application must be signed and dated by an authorized representative of the applicant firm.

Applicant's Statement: I, being duly authorized, have read the above application and declare that to the best of my knowledge that all of the foregoing statements in this application and the information included in all applications, supplements, attachments, supporting information and replies to underwriter inquiries:

1. are true, accurate and complete; and
2. will be relied upon by The Hartford in determining the acceptability of the application and the premium amount to be charged; and
3. will be considered an integral part of the resultant insurance contract

The undersigned further agrees that the applicant has a continuing duty, through date of policy inception, to update this Application, including all supplements, attachments and replies to underwriter inquiries.

## Fraud Warning Statements

Knowingly presenting false or misleading information in an application for insurance may be a crime and violation of law subjecting the applicant to criminal and civil penalties.

**Arkansas, Louisiana, Rhode Island and West Virginia 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.

**Alabama applicants**: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or who knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution, fines, or confinement in prison, or any combination thereof.

**California applicants**: 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.

**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 policy holder 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.

**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.

**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.

**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 there to commits a fraudulent insurance act, which is a crime.

**Maryland applicants**: Any person who knowingly or willfully presents a false or fraudulent claim for payment of a loss or benefit or who knowingly or willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**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.

## Fraud Warning Statements

**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.

**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.

**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.

**Oregon applicants**: Any person who knowingly and with intent to defraud or solicit another to defraud an insurer: (1) by submitting an application or; (2) filing a claim containing a false statement as to any material fact may be violating state law.

**Maine, Tennessee, Virginia, 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.

## Arbitration Statement

Applicable to **Utah applicants**: if the policy will contain an arbitration clause: Any matter in dispute between you and the company may be subject to arbitration as an alternative to court action pursuant to the rules of the (American Arbitration Association or other recognized arbitrator), a copy of which is available on request from the company. Any decision reached by arbitration shall be binding upon both you and the company. The arbitration award may include attorney's fees if allowed by state law and may be entered as a judgment in any court of proper jurisdiction.

| Signature of Authorized Representative: | Signature of Broker/Agent: |
|---|---|
| Print Name: | Print Name: |
| Title: | Title: |
| Date: | Date: |

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