Life Sciences Insurance

Application Form

CHUBB®

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.

You are to disclose in this form fully and faithfully all facts which you know or ought to know, otherwise you may receive nothing from this insurance contract.

Notice: This is an application for a claims made and reported policy and that the limit of liability under any policy to be issued in response hereto shall include both indemnity payments for claims and payment of claim and defense expenses, as defined in the policy.

Please note that the defense cost provision of the policy stipulates that the limits of liability may be completely exhausted by the cost of legal defense. Any deductible or retention shall apply to investigation expense and defense costs as well as indemnity.

All questions in this application must be answered truthfully and completely for all persons or organisations applying for insurance under this application. If a question or section is not applicable, please answer "N/A". 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.

Before continuing, please attach copies of the following with this application:

1. Detailed loss information for the last 5 years
2. Copies of standard and 3 largest sales, service & license contracts or agreements
3. If private, most recent financial statement
4. Protocols and informed consent documents for active sponsored clinical trials
5. Other materials as applicable

General Information

1. Name of Applicant

2. Please provide brief description of your operations.

3. Address

4. Mailing Address (if different from address stated above)

5. Website Address

6. Locations (if other than above)

7. All Named Insureds

8. Additional Insureds (explain relationship)

9. Any acquired subsidiaries in the last 5 years? ☐Yes ☐No

   If **Yes**, please provide entity name and date acquired.

10. Applicant is

    ☐ Individual ☐ Partnership ☐ Corporation ☐ Joint Venture ☐ LLC

    ☐ Other (please describe) _____

11. Years in business? _____

12. Does applicant have a parent company? ☐Yes ☐No

    If **Yes**, please provide name of company.

13. Has applicant operated under another name? ☐Yes ☐No

If **Yes**, please provide full details.

14. Who are applicant's top 3 competitors?

15. Has the applicant filed for bankruptcy in the last seven years? ☐Yes ☐No

If **Yes**, provide full details, including a brief description of the reason for filing, bankruptcy jurisdiction, court number and identity and contact information of the trustee.

16. Is the applicant or any shareholders, directors, officers, partners, or members thereof under any investigation for alleged criminal violations relating to your business? ☐Yes ☐No

17. Is applicant in compliance with all applicable regulatory guidelines? ☐Yes ☐No

If **No**, please provide details.

18. Has applicant been cited for any regulatory violations in the last 3 years? ☐Yes ☐No

If **Yes**, please provide details.

19. Total projected domestic gross sales? $ _____

20. Total projected non-domestic gross sales? $ _____

21. Previous year gross sales? $ _____

Section B – Drugs / Biologics R&D or Product Revenue Percentages

☐ Please tick here if N/A.

	%		%
Single Source Prescription		Single Source Over the Counter	
Multi-Source / Generic Prescription		Multi-Source / Generic Over the Counter	

Specialty Breakdown

	%		%
Cardiology / Vascular Diseases		Oncology	
Dental / Maxillofacial Surgery		Ophthalmology	
Dermatology / Plastic Surgery		Otolaryngology	
Endocrinology		Pediatrics / Neonatology	
Gastroenterology		Pharmacology / Toxicology	
Hematology		Psychiatry / Psychology	
Immunology / Infectious Diseases		Pulmonary / Respiratory Diseases	
Musculoskeletal		Rheumatology	
Nephrology / Urology		Trauma / Emergency Medicine	
Neurology		Obstetrics / Gynecology	
Other			

1. Does applicant have any past, present or planned association with substances in any of the following categories? ☐Yes ☐No

   If **Yes**, provide details.

Category	Association	Category	Association
Known Teratogen	☐Yes ☐No	Vaccines	☐Yes ☐No
Known Mutagen	☐Yes ☐No	Animal Derived	☐Yes ☐No
Known Carcinogen	☐Yes ☐No	Human Derived	☐Yes ☐No
Plant Derived	☐Yes ☐No	Anti-Depressant	☐Yes ☐No
Birth Control	☐Yes ☐No	Hormone	☐Yes ☐No
Weight Reduction	☐Yes ☐No	Addictive Substances	☐Yes ☐No

   Details

Section C - Medical Devices R&D or Product Revenue Percentages

☐ Please tick here if N/A.

	%		%
Anesthesiology		Hematology and Pathology	
Cardiovascular		Immunology and Microbiology	
Clinical Chemistry and Clinical Toxicology		Neurology	
Dental		Obstetrical and Gynecological	
Ear, Nose, and Throat		Ophthalmic	
Gastroenterology and Urology		Orthopedic	
General and Plastic Surgery		Physical Medicine	
General Hospital and Personal Use		Radiology	
Other			

1. Does applicant have any past, present, or planned association with any of the following products? ☐Yes ☐No

If **Yes**, provide details.

Product	Association	Product	Association
Breast Implants	☐Yes ☐No	Spinal Devices	☐Yes ☐No
IUD Devices	☐Yes ☐No	Animal Derived	☐Yes ☐No
Pedicle Screws	☐Yes ☐No	Human Derived	☐Yes ☐No
Latex Gloves	☐Yes ☐No	DEHP	☐Yes ☐No

Details

Section D - Dietary Supplement Product Revenue Percentages

☐ Please tick here if N/A.

Product	%	Product	%
Vitamin		Concentrate, metabolite, constituent or extract	
Mineral		Enzymes	
Herb or other botanical		Medical foods (Prescription required)	
Amino acid		Other	

1. Please identify any of your product categories currently listed on the FDA's Dietary Supplement Warnings and Safety Information Site (http://www.cfsan.fda.gov/~dms/ds-warn.html) or similar regulatory database.

2. Do any of your products contain any animal derived substances? ☐Yes ☐No

3. Do any of your products make health claims? ☐Yes ☐No

   If **Yes**, which ones and have they been published in peer review publications?

4. Have any of your products ever fit the definition of a new dietary ingredient? ☐Yes ☐No

   If **Yes**, have pre-market safety reviews been conducted per regulations?

5. Have any of your products ever had an active ingredient that would be defined as a drug by a regulatory agency? ☐Yes ☐No

   If **Yes**, what are they?

Section E - Professional Service Revenue Percentages

☐ Please tick here if N/A.

Service	%	Service	%
CLIA Certified Lab Services (Indicate type of lab services)		Product Recall / Withdrawal	
Phase 1 Site Services		Clinical Site Management	
Clinical Trials Packaging		Equipment Installation / Maintenance / Sterilisation	
Clinical Site Selection, Training, Monitoring		Quality Systems & Regulatory Compliance	
Communications & Publications		Sales & Marketing	
Health Management, Economic & Policy Research		Software Development or Product Design	

Information Services / Databases		Manufacturing / Distribution / Packaging / Mixing / Labelling	
Institutional Review Board		Pharmacovigilance / Safety Surveillance	
Pre-clinical Services		Warehouse storage	
Financial Services (Please describe)		Other (Please explain)	

1. Does applicant have formalised project-planning policies and procedures? ☐Yes ☐No

2. Does applicant have formalised client complaint resolution policies and procedures? ☐Yes ☐No

3. Are any contracts past due or has a client stopped paying or asked for a refund or credit in the last 3 years? ☐Yes ☐No

   If **Yes**, please provide details.

   _____

4. Total number of current contracts? _____

5. Any discontinued services within the last 10 years? ☐Yes ☐No

   If **Yes**, please provide details.

   _____

6. Average dollar value of applicant's contracts? $ _____

   Average duration of applicant's contracts? _____

7. Indicate largest client for upcoming policy year, and include contract amount / volume and duration.

   _____

8. What is the total value of the personal property of others at applicant's facilities? $ _____

   Details _____

Section F - Drug Discovery Technology R&D or Product Revenue Percentages

☐ Please tick here if N/A.

Bioinformatics	%	Proteomic	%	Genomics	%
Software		Software		Software	
Hardware		Hardware		Hardware	
Data		Data		Data	
Other					

Details _____

Section G - Research Institutions Revenues / Funding

☐ Please tick here if N/A.

Service	%	Service	%
Product Licensing		Product Commercialisation	
Basic Research		Medical Product Research	
Pre-clinical Testing		Non Medical Product Research	
Clinical Testing		Other	

Details _____

Section H - Supplier and/or Wholesale Distributor Revenue Percentages

☐ Please tick here if N/A.

Service	%	Service	%
Drugs / Biologics		Medical Device Component Parts / Software	
Medical Devices		Drugs / Biologic Ingredients	
Dietary Supplements		Medical Products Manufacturing Equipment	
Active Ingredients		Medical Products R&D Equipment	
Other			

1. If you are a supplier of components or ingredients, or a distributor for the products of others, do you require additional insured status on the product license holder's products liability policy? ☐Yes ☐No

   Do you require indemnification for damages including defense cost? ☐Yes ☐No

   Details _____

Section I - Human Clinical Trials

☐ Please tick here if N/A.

Active Trials Currently Being Sponsored. (Include phase 4)

Product Name & Protocol Number	No. of New Enrollees Over Next Policy Period	Indication	Trial Phase	Country(ies)	Number of sites

1. Number of expanded access / compassionate use participants anticipated in the coming policy term? _____

2. Total number of completed human clinical trials applicant sponsored in last 3 years _____

3. Total number of human participants enrolled in the last 3 years _____

4. Any clinical trials past, present, or planned involving minors? _____

5. Any clinical trials discontinued or suspended due to safety reasons? ☐Yes ☐No

   If **Yes**, please provide details.

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6. What are the minimum standards for Clinical Investigator selection requirements? _____

7. Have any Clinical Investigators been cited for regulatory violations in connection with your trials? ☐Yes ☐No

   If **Yes**, please provide details.

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8. Has applicant had any evidence of serious regulatory non-compliance or fraud by Clinical Investigators in connection with your trials in the past 5 years? ☐Yes ☐No

   If **Yes**, please provide details.

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9. Number of clinical trial "For Cause Audits" conducted by applicant or regulatory agency in the last 5 years? _____

10. Do you provide Clinical Investigators with compensation other than charges for specific services rendered, such as enrollment bonuses, equity interest, etc.? ☐Yes ☐No

11. What is the targeted reading grade level for your informed consent documents? _____

12. Does applicant require Clinical Investigators to test participants on their understanding of the informed consent document? ☐Yes ☐No

13. Does applicant incorporate financial disclosures in the informed consent documents or process? ☐Yes ☐No

14. What has been the maximum compensation applicant has offered trial participants? $ _____

15. Who monitors compliance with the individual state and country clinical trial regulations?

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16. Does applicant have formalised Clinical Trial Suspension SOP's in place? ☐Yes ☐No

17. Do any of applicant's employees or sub-contractors provide direct patient care on applicant's behalf? ☐Yes ☐No

    Do they carry their own medical malpractice insurance? ☐Yes ☐No

18. Does applicant ever act as both trial sponsor and clinical investigator? ☐Yes ☐No

19. Does applicant provide material / product, or both, for clinical trials for trials you do not sponsor? ☐Yes ☐No

20. Does applicant operate an in-patient facility? ☐Yes ☐No

    If **Yes**, does applicant have an accredited emergency care facility? ☐Yes ☐No

21. In the last 3 years have applicant published any study results without including other studies that were conducted by applicant that did not support the same findings? ☐Yes ☐No

    If **Yes**, please provide details.

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22. Does the applicant publish all clinical trial results? ☐Yes ☐No

23. Is applicant in compliance with all applicable regulatory guidelines? ☐Yes ☐No

    If **No**, please provide details.

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24. Has applicant been cited for any regulatory violations in the last 3 years? ☐Yes ☐No

    If **Yes**, please provide details.

Section J - Medical Staff Profile

☐ Please tick here if N/A.

Health professionals	Specialty	Est. hours of direct patient interactions annually	No. of Applicant Employees	No. of Independent Contractors
Physicians				
RNs				
LPNs				
Pharmacist				
Medical Technician				
EMTs				
Others (please describe)				

Section K - Legal

1. Does applicant have any contracts that:

    a. Assume the tort liability of another party ☐Yes ☐No

    b. Does not limit damages to direct damages only ☐Yes ☐No

c. Does not extend Force Majeure to any and all events outside applicant's control ☐Yes ☐No

d. Does not indicate a mutual hold harmless agreement ☐Yes ☐No

If you answered **Yes** to any of the questions above, please explain.

2. Does applicant use a written contract or agreement with all clients, including changes? ☐Yes ☐No

3. Does applicant's attorney review all contracts or agreements including changes prior to use? ☐Yes ☐No

4. Are there formal incidents and claims escalation procedures in place? ☐Yes ☐No

5. Are there formal procedures in place regarding litigation document control? ☐Yes ☐No

6. Is there formal training on internal and external communication policies and procedures? ☐Yes ☐No

Section L - Product Sales & Marketing

☐ Please tick here if N/A.

1. Projected annual prescriptions/units to be sold? _____

2. Projected number of annual products users? _____

3. Any product ingredients/components imported? ☐Yes ☐No

If **Yes**, please provide details.

4. Any products manufactured sold under others' labels? ☐Yes ☐No

If **Yes**, please provide details.

5. Any products sold as ingredients/components for other products? ☐Yes ☐No

If **Yes**, please provide details.

6. Any products manufactured outside the domestic country? ☐Yes ☐No

If **Yes**, please provide details.

7. Any products approved for use by minors? ☐Yes ☐No

8. Any products discontinued for safety reasons? ☐Yes ☐No

   If **Yes**, please provide details.

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9. Any association with banned products? ☐Yes ☐No

   If **Yes**, please provide details.

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10. How many product recalls has applicant had in the past 3 years? _____

    Describe in detail any Class 1 recalls.

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11. Indicate the top 3 products in terms of number of Adverse Event Reports where the product was associated with a death, permanent injury, or hospitalisation outcome. Please provide copy of most recently completed Safety Report associated with these products.

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12. Identify any product requiring the addition of a black box or other significant safety warning to existing labeling or instruction manuals in the last 3 years.

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13. Identify any safety surveillance team recommendations involving any of the following forms of remedial actions that have yet to be implemented or completed: product recall / withdrawal, black box warning label, "Healthcare Professional" letter, additional studies, or expanded product monitoring.

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14. What steps if any would the company take if applicant became aware of a pervasive off-label use of applicant's products?

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15. Please indicate known revenues from off-label use of your products.

16. Does the company allow any off-label information dissemination? ☐Yes ☐No

17. Have there been any incidents of non-compliance regarding regulations concerning sales and marketing practices by either internal or external product sales personnel? ☐Yes ☐No

18. How often are compliance audits performed on your internal and external sales staff? _____

19. Do compliance audits include follow-up discussions with physicians? ☐Yes ☐No

20. What % of the company's advertising budget is allocated to Direct to Consumer (DTC) advertising? _____

21. Is there a required waiting period after product launch before DTC is conducted? ☐Yes ☐No

22. What are the top 3 most expensive perks applicant provide to physicians?

23. Does applicant have formal policy specifically prohibiting physical patient contact by internal and external product sales personnel? ☐Yes ☐No

    Have there been any incidents of non-compliance in the last 3 years? ☐Yes ☐No

24. How often is formal and documented compliance training required of your internal and external sales force? _____

Section M - Operations Risk Management & Loss Control

1. Does applicant have a formalised Enterprise Risk / Safety Programme? ☐Yes ☐No

   If **Yes,** please provide name of person in charge of programme.

2. What are the main focal areas of your Enterprise Risk / Safety Programme? (Areas might include Code of Conduct, Privacy, Biohazards, Disaster Recovery, etc.)

3. Does applicant require all new employees participate in training program that instructs them on all applicable company policies and procedures? ☐Yes ☐No

4. Does applicant require Certificates of Insurance from all of applicants' suppliers and sub-contractors? ☐Yes ☐No

   What limits and terms does applicant require?

   _____

   _____

5. Are all risk management programmes and SOP's audited annually? ☐Yes ☐No

6. Please indicate any risk management programmes and SOPs that are audited by independent non-governmental organisations / individuals? ☐Yes ☐No

7. Indicate Industry Trade Associations Memberships.

   _____

8. Does applicant have a crisis management team in place? ☐Yes ☐No

9. Does applicant have a full time risk manager on staff? ☐Yes ☐No

Section N - Premises / Operations

☐ Please tick here if N/A.

1. Indicate which of the following applies to applicant's premises:

   ☐ Access is not allowed without card and/or authorised employee

   ☐ Front desk registration only

   ☐ No restricted access.

2. Indicate which of the following applies:

   ☐ Hazardous substances are kept outdoors or in a cut-off within approved containers

   ☐ Just in time supply levels

   ☐ Cut-off area with unapproved containers

3. Indicate how many gallons of hazardous substances are kept on site? ☐Yes ☐No

4. Biohazard Lab Rating if applicable? _____

5. Do you have an animal facility or house animals? ☐Yes ☐No

6. If applicable is the applicant in compliance with Hazardous Materials Regulations? ☐Yes ☐No

7. Has applicant ever hired key employees from direct competitors? ☐Yes ☐No

8. Does applicant ever do direct product comparisons against competitor products? ☐Yes ☐No

9. Does applicant have any competitors making similar products? ☐Yes ☐No

10. Does applicant have a formalised Privacy Policy in place? ☐Yes ☐No

If **Yes**, when was it last updated and audited? _____

Section O - Property

☐ Please tick here if N/A.

Answers to these industry-specific questions are requested as a supplement to standard industry (e.g. Acord) Property and Business Income applications.

1. **Change In Controlled Environment - Perishable Property**: Is perishable property (e.g. reagents, cell cultures, work-in-process or stock) with an estimated financial impact (replacement cost value plus resulting business income loss) in excess of $250,000 stored at any single location? If **No**, proceed to question #7. ☐Yes ☐No

2. What is the estimated maximum property damage and resulting business income loss which would result from a total loss of perishable property at any single location? _____

3. Is all perishable property monitored by a UL listed central station temperature alarm, programmed to activate in the event of both low and high temperatures, with protection operational at all times? ☐Yes ☐No

4. Is temperature alarm effectiveness ensured through a regular maintenance programme with, at a minimum, annual scheduled testing? ☐Yes ☐No

5. Are automatic, self-starting, non-electric back-up power units providing a minimum 24-hour power supply to all perishable property operational and load testing at least annually? ☐Yes ☐No

6. Is a specific, pre-planned emergency response action plan in place and practiced at least annually to ensure rapid and effective intervention by trained personnel to failure of building support systems and resulting temperature emergencies? ☐Yes ☐No

7. **Scientific Animals**: Are animals with replacement cost value (cost of purchasing a replacement animal plus any increase in the animal value as a result of your R&D operations, or selling price if animals are stock) in excess of $100,000 housed at any single location? If **No**, proceed to question #14. ☐Yes ☐No

8. What is the estimated maximum property damage loss which would result from a total loss of an animal colony at any single location? _____

9. Is access to all animal facilities restricted electronically to employees whose job functions require them to work in that area? ☐Yes ☐No

10. Do the animal facilities have dedicated environmental control (including HVAC / air handling) systems, with an automatic, self starting back-up power source and UL listed central station alarms, with protection operational at all times? ☐Yes ☐No

11. Are UL listed central station smoke alarms operational throughout the buildings where animals are housed, and are smoke dampers installed within the HVAC system to keep smoke which emanates from outside the animal lab from impacting the animals? ☐Yes ☐No

12. Are the animal facilities monitored by a UL listed central station temperature alarm, programmed to activate in the event of both low and high temperatures, with protection operational at all times? ☐Yes ☐No

13. Are critical colonies separated into distinct facilities, or are embryonic cells of critical colonies cryogenically preserved off-site? ☐Yes ☐No

14. **Research and Development Income**: Does the applicant anticipate earning any grants, endowments or financial contributions from third parties during the period of insurance, the payment of which is contingent upon attaining contractually stipulated R&D milestones? If **No**, proceed to question #17. ☐Yes ☐No

15. To the extent that insurance is requested for R&D Income described in #14 above, what is the total dollar value of the contracts which are expected to become payable during the period of insurance? Please note that a schedule of these contracts (title and R&D income value) must be reported to trigger R&D Income coverage under the policy. This information may be attached as an addendum to this application. ☐Yes ☐No

16. What is the largest Personal Property of Others value at any single location?

17. Does applicant ship any perishable property, narcotics or live animals at their own risk? ☐Yes ☐No

18. To the extent that coverage in transit is requested for property described in #17 above, please provide full commodity, packaging, value and common carrier information.

Section P - Loss History & Potential Loss

Policy Period	Insurer	No. of Claims	Total Incurred	Total Paid	Loss Ratio

* Total aggregate cost (losses from ground up including defense, deductibles, and SIR's) for last five years.

* Attach previous carrier loss runs.

1. Describe all incurred losses of $10,000 or more

2. Any claims not yet reported? ☐Yes ☐No

If **Yes**, please provide details.

3. Indicate any product or service past or present that has been involved with any certified, or attempted, class action or multi-district litigation?

4. 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? ☐Yes ☐No

   If **Yes**, please provide details.

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.

Section Q - Coverage History

Policy Period	Primary & Excess Limits	Carriers	Occurrence/Claims Made	Retro Date

1. Does applicant have any outstanding loss control recommendations with applicant's current carrier? ☐Yes ☐No

   If **Yes**, please provide details.

2. Has applicant's insurance ever been canceled or non-renewed by a carrier? ☐Yes ☐No

   If **Yes**, please provide details.

3. Any of your products, clinical trials, or services specifically excluded on your existing policy? ☐Yes ☐No

   If **Yes**, please provide details.

4. Have you had concurrent claims made insurance for the insurance you are requesting back to your stated retro date? ☐Yes ☐No

Section R - Insurance Requested

Coverage	Limits Requested	Deductible/SIR Requested
Premises & Operations Liability		
Products & Completed Operations Liability		
Professional Liability (E&O Financial Injury)		
Property		
Other		

Details

Applicant Acknowledgement

Information or data contained in or submitted in connection with this application (or otherwise to any of the member insurers of Chubb group of insurance companies ("Chubb") in connection with the underwriting process) does not constitute notice of an occurrence, wrongful act, claim, suit or other circumstance and does not satisfy any of the reporting notification or other provisions of any policy. All such notices must be given separately in accordance with the applicable policy conditions.

For the purposes of this application, the above-signed officer of all person(s) and organisation(s) proposed for this insurance declares and acknowledges by executing this application that, no alterations were made to this application (other than sections reserved for answers), he/she has reviewed this application and the statements contained therein with his/her Chief Executive Officer, Chief Financial Officer, Chief Operating Officer or their equivalents, and that to the best of their knowledge and belief, after reasonable inquiry, the statements in this application, and in any attachments, are true and complete for all persons or organisations applying for insurance under this application. Chubb is authorised to make any inquiry in connection with this application. Signing this application shall not constitute a binder or obligate Chubb to complete this insurance, but it is agreed this application shall be the basis upon which a policy may be issued. If the statements in this application or in any attachment change materially before the effective date of any proposed policy, the applicant must notify Chubb, and Chubb may modify or withdraw any quotation.

Authorised Signature of Applicant

Date

Print Name

Title

Applicant

Authorised Agent (Please Print Name)

Authorised Agent (Signature)

Title

Date

Submitted By (Insurance Agent)

Insurance Agency

Address

Date

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