



# Life Sciences New Business Application

Chubb  
202 Halls Mill Rd  
Whitehouse Station, New Jersey 08889

**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 organizations applying for insurance under this application. If a question or section is not applicable, please answer "na". If the answer to a question is none, state "none" or "o". If more space is required to answer a question completely, please provide a separate attachment and identify the question it responds to.**

*This application is a word document that allows applicant to enter information in the empty sections. Any alteration of this application (other than sections reserved for answers) is expressly prohibited. This document is configured so that each data entry section will expand to accommodate the information. A box for detailed commentary has been provided below each major section of the application.*

## **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. Applicant:                                                                                                      |                                                                                                                                                                                                                                   |
| 2. Please provide brief description of your operations:                                                            |                                                                                                                                                                                                                                   |
| 3. Address:                                                                                                        |                                                                                                                                                                                                                                   |
| 4. Mailing Address: <i>(if different)</i>                                                                          |                                                                                                                                                                                                                                   |
| 5. Web Site Address:                                                                                               |                                                                                                                                                                                                                                   |
| 6. Locations: <i>(if other than above)</i>                                                                         |                                                                                                                                                                                                                                   |
| 7. All Named Insureds:                                                                                             |                                                                                                                                                                                                                                   |
| 8. Additional Insureds: <i>(explain relationship)</i>                                                              |                                                                                                                                                                                                                                   |
| 9. Any acquired subsidiaries in the last 5 years?<br><i>(if yes, please provide entity name and date acquired)</i> |                                                                                                                                                                                                                                   |
| 10. Applicant is:                                                                                                  | <input type="checkbox"/> Individual <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation<br><input type="checkbox"/> Joint Venture <input type="checkbox"/> LLC <input type="checkbox"/> Other<br>(describe) |
| 11. Years in business?                                                                                             |                                                                                                                                                                                                                                   |

|                                                                                                                                                                                                                                                          |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 12. Does applicant have a parent company? (if yes, provide name)                                                                                                                                                                                         |  |
| 13. Has applicant operated under another name? (if yes, provide full details)                                                                                                                                                                            |  |
| 14. Who are applicant's top 3 competitors?                                                                                                                                                                                                               |  |
| 15. Has the applicant filed for bankruptcy in the last seven years?<br>(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?                                                                           |  |
| 17. Is applicant in compliance with all applicable regulatory guidelines?<br>(if no, provide details)                                                                                                                                                    |  |
| 18. Has applicant been cited for any regulatory violations in the last 3 years?<br>(if yes, provide details)                                                                                                                                             |  |
| 19. Total projected domestic gross sales?                                                                                                                                                                                                                |  |
| 20. Total projected non-domestic gross sales?                                                                                                                                                                                                            |  |
| 21. Previous year gross sales?                                                                                                                                                                                                                           |  |

**Drugs/Biologics R&D or Product Revenue Percentages.** If N/A indicate here: ☐

|                                   |  |                                       |  |
|-----------------------------------|--|---------------------------------------|--|
| 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                      |  | Other                          |  |
| Obstetrics/Gynecology          |  |                                |  |

Does applicant have any past, present or planned association with substances in any of the following categories: (if yes, provide details)

|                  |  |                |  |                  |  |                      |  |
|------------------|--|----------------|--|------------------|--|----------------------|--|
| Known Teratogen  |  | Vaccines       |  | Plant Derived    |  | Anti-Depressant      |  |
| Known Mutagen    |  | Animal Derived |  | Birth Control    |  | Hormone              |  |
| Known Carcinogen |  | Human Derived  |  | Weight Reduction |  | Addictive Substances |  |

Details:

**Medical Devices R&D Or Product Revenue Percentages.** If N/A Indicate Here: ☐

|                                            |  |                               |  |
|--------------------------------------------|--|-------------------------------|--|
| 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: (if yes, provide details)

|                 |  |                |  |              |  |  |
|-----------------|--|----------------|--|--------------|--|--|
| Breast Implants |  | Spinal Devices |  | Latex Gloves |  |  |
| IUD Devices     |  | Animal Derived |  | DEHP         |  |  |
| Pedicle Screws  |  | Human Derived  |  |              |  |  |

Details:

**Dietary Supplement Product Revenue Percentages.** *If N/A indicate here:* ☐

|                         |  |                                                 |  |
|-------------------------|--|-------------------------------------------------|--|
| 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?

3. Do any of your products make health claims? 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? If so, 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? If so, what are they?

Details:

**Professional Service Revenue Percentages.** *If N/A indicate here:* ☐

|                                                             |  |                                                  |  |
|-------------------------------------------------------------|--|--------------------------------------------------|--|
| 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/Sterilization |  |
| 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                              |  | Manuf./Distribution/Packaging/Mixing/Labeling    |  |
| Institutional Review Board                                  |  | Pharmacovigilance/Safety Surveillance            |  |
| Pre-clinical Services                                       |  | Warehouse storage                                |  |
| Financial Services (please describe)                        |  | Other (please explain)                           |  |
|                                                             |  |                                                  |  |

1. Does applicant have formalized project-planning policies and procedures?

2. Does applicant have formalized client complaint resolution policies and procedures?

3. Are any contracts past due or has a client stopped paying or asked for a refund or credit in the last 3 years? (if yes, provide details)

4. Total # of current contracts?

5. Any discontinued services within the last 10 years? (if yes, 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:

**Drug Discovery Technology R&D Or Product Revenue Percentages.** *If N/A indicate here:* ☐

|                |  |             |  |             |  |
|----------------|--|-------------|--|-------------|--|
| Bioinformatics |  | Proteomic   |  | Genomics    |  |
| • Software:    |  | • Software: |  | • Software: |  |
| • Hardware:    |  | • Hardware: |  | • Hardware: |  |
| • Data:        |  | • Data:     |  | • Data:     |  |

Other:

Details:

**Research Institutions Revenues/Funding.** *If N/A indicate here:* ☐

|                      |  |                              |  |
|----------------------|--|------------------------------|--|
| Product Licensing    |  | Product Commercialization    |  |
| Basic Research       |  | Medical Product Research     |  |
| Pre-clinical Testing |  | Non-Medical Product Research |  |
| Clinical Testing     |  | Other                        |  |

Details:

**Supplier and/or Wholesale Distributor Revenue Percentages.** *If N/A indicate here:* ☐

|                     |  |                                          |  |
|---------------------|--|------------------------------------------|--|
| 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 a supplier of components or ingredients, or a distributor for the products of others, do require additional insured status on the product license holder's products liability policy? Do you require indemnification for damages including defense cost?

Details:

**Human Clinical Trials.** *If N/A indicate here:* ☐

Active Trials Currently Being Sponsored. (include phase 4)

| Product Name & Protocol Number | # of New Enrollees Over Next Policy Period | Indication | Trial Phase | Country(ies) | Number of sites |
|--------------------------------|--------------------------------------------|------------|-------------|--------------|-----------------|
|                                |                                            |            |             |              |                 |
|                                |                                            |            |             |              |                 |
|                                |                                            |            |             |              |                 |
|                                |                                            |            |             |              |                 |
|                                |                                            |            |             |              |                 |
|                                |                                            |            |             |              |                 |

- Number of expanded access/compassionate use participants anticipated in the coming policy term?
- Total number of completed human clinical trials applicant sponsored in last 3 years:
- Total number of human participants enrolled in the last 3 years:
- Any clinical trials past, present, or planned involving minors?
- Any clinical trials discontinued or suspended due to safety reasons? *(if yes, provide details)*
- What are the minimum standards for Clinical Investigator selection requirements?
- Have any Clinical Investigators been cited for regulatory violations in connection with your trials? *(if yes, provide details)*
- 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? *(if yes, provide details)*
- Number of clinical trials "For Cause Audits" conducted by applicant or regulatory agency in the last 5 years?
- Do you provide Clinical Investigators with compensation other than charges for specific services rendered, such as enrollment bonuses, equity interest, etc.?

|                                                                                                                                                                                                       |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 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?                                                                       |  |
| 13. Does applicant incorporate financial disclosures in the informed consent documents or process?                                                                                                    |  |
| 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?                                                                                                         |  |
| 16. Does applicant have formalized Clinical Trial Suspension SOP's in place?                                                                                                                          |  |
| 17. Do any of applicant's employees or sub-contractors provide direct patient care on applicant's behalf?<br>Do they carry their own medical malpractice insurance?                                   |  |
| 18. Does applicant ever act as both trial sponsor and clinical investigator?                                                                                                                          |  |
| 19. Does applicant provide material/product, or both, for clinical trials for trials you do not sponsor?                                                                                              |  |
| 20. Does applicant operate an in-patient facility? If so, does applicant have an accredited emergency care facility?                                                                                  |  |
| 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? (if yes, provide details) |  |
| 22. Does the applicant publish all clinical trial results?                                                                                                                                            |  |
| 23. Is applicant in compliance with all applicable regulatory guidelines? (if no, provide details)                                                                                                    |  |
| 24. Has applicant been cited for any regulatory violations in the last 3 years? (if yes, provide details)                                                                                             |  |

Details:

**Medical Staff Profile.** *If N/A indicate here:* ☐

| Health professionals     | Specialty | Est. hours of direct patient interactions annually | # Applicant Employees | # Independent Contractors |
|--------------------------|-----------|----------------------------------------------------|-----------------------|---------------------------|
| Physicians               |           |                                                    |                       |                           |
| RN's                     |           |                                                    |                       |                           |
| LPN's                    |           |                                                    |                       |                           |
| Pharmacist               |           |                                                    |                       |                           |
| Medical Technician       |           |                                                    |                       |                           |
| EMT's                    |           |                                                    |                       |                           |
| Others (please describe) |           |                                                    |                       |                           |

Details:

**Legal**

1. Does applicant have any contracts that: *(if so, please explain)*

|                                                                                                 |  |
|-------------------------------------------------------------------------------------------------|--|
| a. Assume the tort liability of another party                                                   |  |
| b. Does not limit damages to direct damages only                                                |  |
| c. Does not extend Force Majeure to any and all events outside applicant's control              |  |
| d. Does not indicate a mutual hold harmless agreement                                           |  |
| 1. Does applicant use a written contract or agreement with all clients, including changes?      |  |
| 2. Does applicant's attorney review all contracts or agreements including changes prior to use? |  |
| 3. Are there formal incidents and claims escalation procedures in place?                        |  |
| 4. Are there formal procedures in place regarding litigation document control?                  |  |
| 5. Is there formal training on internal and external communication policies and procedures?     |  |

Details:

**Product Sales & Marketing.** *If N/A indicate here:* ☐

|                                                     |  |
|-----------------------------------------------------|--|
| 1. Projected annual prescriptions/units to be sold? |  |
|-----------------------------------------------------|--|

|                                                                                                                                                                                                                                                                                                            |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 2. Projected # of annual products users?                                                                                                                                                                                                                                                                   |  |
| 3. Any product ingredients/components imported? <i>(if yes, provide details)</i>                                                                                                                                                                                                                           |  |
| 4. Any products manufactured sold under others' labels? <i>(if yes, provide details)</i>                                                                                                                                                                                                                   |  |
| 5. Any products sold as ingredients/components for other products? <i>(if yes, provide details)</i>                                                                                                                                                                                                        |  |
| 6. Any products manufactured outside the domestic country? <i>(if yes, provide details)</i>                                                                                                                                                                                                                |  |
| 7. Any products approved for use by minors?                                                                                                                                                                                                                                                                |  |
| 8. Any products discontinued for safety reasons? <i>(if yes, provide details)</i>                                                                                                                                                                                                                          |  |
| 9. Any association with banned products? <i>(if yes, provide details)</i>                                                                                                                                                                                                                                  |  |
| 10. How many product recalls has applicant had in the past 3 years? Describe in detail any Class 1 recalls?                                                                                                                                                                                                |  |
| 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 hospitalization outcome? Please provide copy of most recently completed Safety Report associated with these products.                                      |  |
| 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?                                                                                                                                        |  |
| 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. |  |
| 14. What steps if any would the company take if applicant became aware of a pervasive off-label use of applicant's products?                                                                                                                                                                               |  |
| 15. Please indicate known revenues from off-label use of your products.                                                                                                                                                                                                                                    |  |
| 16. Does the company allow any off-label information dissemination?                                                                                                                                                                                                                                        |  |
| 17. Have there been any incidents of non-compliance regarding regulations concerning sales and marketing practices by either internal or external product sales personnel?                                                                                                                                 |  |
| 18. How often are compliance audits performed on your internal and external sales staff?                                                                                                                                                                                                                   |  |
| 19. Do compliance audits include follow-up discussions with physicians?                                                                                                                                                                                                                                    |  |
| 20. What % of the company's advertising budget is allocated to Direct to Consumer advertising?                                                                                                                                                                                                             |  |
| 21. Is there a required waiting period after product launch before DTC is conducted?                                                                                                                                                                                                                       |  |
| 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? Have there been any incidents of non-compliance in the last 3 years?                                                                                             |  |
| 24. How often is formal and documented compliance training required of your internal and external sales force?                                                                                                                                                                                             |  |

### **Operations Risk Management & Loss Control**

|                                                                                                                                                                     |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 1. Does applicant have a formalized Enterprise Risk/Safety Program? <i>(if yes please provide name of person in charge of program)</i>                              |  |
| 2. What are the main focal areas of your Enterprise Risk/Safety Program? <i>(Areas might include Code of Conduct, Privacy, Biohazards, Disaster Recovery, etc.)</i> |  |
| 3. Does applicant require all new employees participate in training program that instructs them on all applicable company policies and procedures?                  |  |
| 4. Does applicant require Certificates of Insurance from all of applicants' suppliers and sub-contractors? What limits and terms does applicant require?            |  |
| 5. Are all risk management programs and SOP's audited annually?                                                                                                     |  |
| 6. Please indicate any risk management programs and SOP's that are audited by independent non-governmental organizations/individuals?                               |  |
| 7. Indicate Industry Trade Associations Memberships.                                                                                                                |  |
| 8. Does applicant have a crisis management team in place?                                                                                                           |  |

|                                                           |  |
|-----------------------------------------------------------|--|
| 9. Does applicant have a full-time risk manager on staff? |  |
|-----------------------------------------------------------|--|

Details:

**Premises/Operations.** *If N/A indicate here:* ☐

|                                                                                                                                                                                                     |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 1. Indicate which of the following applies to applicant's premises: access is not allowed without card and/or authorized employee, front desk registration only, or 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?                                                                                                                              |  |
| 4. Biohazard Lab Rating if applicable?                                                                                                                                                              |  |
| 5. Do you have an animal facility or house animals?                                                                                                                                                 |  |
| 6. If applicable is the applicant in compliance with Hazardous Materials Regulations?                                                                                                               |  |
| 7. Has applicant ever hired key employees from direct competitors?                                                                                                                                  |  |
| 8. Does applicant ever do direct product comparisons against competitor products?                                                                                                                   |  |
| 9. Does applicant have any competitors making similar products?                                                                                                                                     |  |
| 10. Does applicant have a formalized Privacy Policy in place? When was it last updated and audited?                                                                                                 |  |

Details:

**Property.** *If N/A indicate here:* ☐

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

|                                                                                                                                                                                                                                                                                                                                       |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 1. <b>Change in Controlled Environment - Perishable Property:</b> 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 |  |
| 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?                                                                                                                            |  |
| 4. Is temperature alarm effectiveness ensured through a regular maintenance program with, at a minimum, annual scheduled testing?                                                                                                                                                                                                     |  |
| 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?                                                                                                                                                 |  |
| 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?                                                                                   |  |
| 7. <b>Scientific Animals:</b> 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                  |  |
| 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?                                                                                                                                                                                                   |  |
| 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?                                                                                      |  |
| 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?                                                                             |  |
| 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?                                                                                                                            |  |

|     |                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 13. | Are critical colonies separated into distinct facilities, or are embryonic cells of critical colonies cryogenically preserved off-site?                                                                                                                                                                                                                                                                                                    |  |
| 14. | <b>Research and Development Income:</b> 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                                                                                                                               |  |
| 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?<br><i>Please note that a schedule of these contracts (title and R&amp;D income value) must be reported to trigger R&amp;D Income coverage under the policy. This information may be attached as an addendum to this application.</i> |  |
| 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?                                                                                                                                                                                                                                                                                                                                                  |  |
| 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.                                                                                                                                                                                                                                                                   |  |

Details:

### Loss History & Potential Loss

| Policy Period | Insurer | # 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? <i>(if yes, provide details)</i>                                                                                                                                                                   |  |
| 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? <i>(if yes, provide details)</i> |  |

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

### 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? <i>(if yes, provide details)</i> |  |
| 2. | Has applicant's insurance ever been canceled or non-renewed by a carrier? (if yes, provide details)                                 |  |
| 3. | Any of your products, clinical trials, or services specifically excluded on your existing policy? (if yes, provide details)         |  |
| 4. | Have you had concurrent claims made insurance for the insurance you are requesting back to your stated retro date?                  |  |

Details:

**Insurance Requested**

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

**Chubb is the marketing name used to refer to subsidiaries of Chubb Limited providing insurance and related services. For a list of these subsidiaries, please visit our website at**

**[www.chubb.com](http://www.chubb.com). Insurance provided by ACE American Insurance Company and its U.S. based Chubb underwriting company affiliates. All products may not be available in all states. This communication contains product summaries only. Coverage is subject to the language of the policies as actually issued.**

For the purposes of this application, the above-signed officer of all person(s) and organization(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 organizations applying for insurance under this application. Chubb is authorized 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.

|                                                     |                                                                                                        |      |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------|------|
| Authorized Signature of Applicant                   | Date                                                                                                   |      |
| Print Name                                          | Title                                                                                                  |      |
| Applicant                                           | Authorized Agent (Please Print Name)                                                                   |      |
| Authorized Agent (Signature)                        | Title                                                                                                  | Date |
| Submitted By (Insurance Agent)                      | Insurance Agency                                                                                       |      |
| Insurance Agency Taxpayer ID or Social Security No. | Agent License No. (For non-admitted placements a copy of valid surplus lines license will be required) |      |
| Address (No., Street, City, State, and ZIP Code)    |                                                                                                        |      |

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**NOTICE TO COMMERCIAL INSURANCE APPLICANTS**

**This Notice to Commercial Insurance Applicants – State Fraud Warnings provides you with information concerning various state fraud warnings and statements. Where fraud warnings are required as part of the insurance application, this notice forms a part of your application for Commercial Insurance.**

**NOTICE TO 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 AND CONFINEMENT IN PRISON, OR ANY COMBINATION THEREOF.

**NOTICE TO ARKANSAS 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 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.

**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 OF THE THIRD DEGREE.

**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 A DENIAL OF INSURANCE BENEFITS.

**NOTICE TO 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.

**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 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 SHALL ALSO BE SUBJECT TO A CIVIL PENALTY NOT TO EXCEED FIVE THOUSAND DOLLARS AND THE STATED VALUE OF THE CLAIM FOR EACH VIOLATION.

**ADDITIONAL NOTICE TO NEW YORK COMMERCIAL AUTO APPLICANTS:** 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, AND ANY PERSON WHO, IN CONNECTION WITH SUCH APPLICATION OR CLAIM, WHO KNOWINGLY MAKES OR KNOWINGLY ASSISTS, ABETS, SOLICITS OR CONSPIRES WITH ANOTHER TO MAKE A FALSE REPORT OF THEFT, DESTRUCTION, DAMAGE OR CONVERSION OF ANY MOTOR VEHICLE TO A LAW ENFORCEMENT AGENCY THE DEPARTMENT OF MOTOR VEHICLES OR AN INSURANCE COMPANY COMMITS A FRAUDULENT INSURANCE ACT, WHICH IS A CRIME, AND SHALL ALSO BE SUBJECT TO A CIVIL PENALTY NOT TO EXCEED FIVE THOUSAND DOLLARS AND THE VALUE OF THE SUBJECT MOTOR VEHICLE OR STATED CLAIM FOR EACH 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 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 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.

**ADDITIONAL NOTICE TO PENNSYLVANIA COMMERCIAL AUTO APPLICANTS:** ANY PERSON WHO KNOWINGLY AND WITH INTENT TO DEFRAUD ANY INSURER FILES AN APPLICATION OR CLAIM CONTAINING ANY FALSE, INCOMPLETE OR MISLEADING INFORMATION SHALL, UPON CONVICTION, BE SUBJECT TO IMPRISONMENT FOR UP TO SEVEN YEARS AND PAYMENT OF A FINE OF UP TO \$15,000.

**NOTICE TO RHODE ISLAND 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 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.

**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 MAY INCLUDE IMPRISONMENT, FINES AND DENIAL OF INSURANCE BENEFITS.

**NOTICE TO 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.

**NOTICE TO APPLICANTS IN STATES NOT LISTED ABOVE:** 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 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.

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