



Small Business – Life Sciences

Manufacturing and Distributors Application

This is an application for a CLAIMS MADE POLICY. Should this application be accepted by the company, coverage will apply to claims first made against the insured during the policy period. No coverage will apply for claims first made against the insured after the end of the policy period unless the extended reporting period applies. No coverage will apply for claims first made prior to the retroactive date shown in the declarations of the policy. The completion and submission of this application to the company does not constitute a binder of insurance. All questions must be answered.

If a question is not applicable, answer N/A. If the answer to the 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.

Applicant Information

Applicant's Legal Name _____

Applicant's Location Address _____

Address Line 2 _____

City, State, ZIP Code _____

If mailing address is not the same as the location address, enter the mailing address below.

Applicant's Mailing Address _____

Address Line 2 _____

City, State, ZIP Code _____

Contact Phone Number _____

Email Address _____

Website Address _____

Legal Entity Type _____

Years in Business _____

Description of Operations _____

If any acquisitions/mergers have occurred in the last 5 years, list below.

| Acquisition Company Name | Acquisition Date |
|--------------------------|------------------|
| | |
| | |
| | |

Current Policy Information

Effective Date _____ Expiration Date _____

Retroactive Date _____

If coverage with a prior carrier exists, list below.

Prior Carrier _____

Effective Date _____

Expiration Date _____

Limit Type _____

Each Claim Limit _____

Each Claim Deductible _____

Each Claim SIR _____

Aggregate Limit _____

Aggregate Deductible _____

Aggregate SIR _____

Retroactive Date _____

List any paid, reserved or pending claim activity not yet reported to current carrier.

| Date of Claim | Type/Description of Claim | Estimated Amount of Claim | Carrier |
|---------------|---------------------------|---------------------------|---------|
| | | | |
| | | | |
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If the applicant has additional entities to be included as “Named Insureds,” schedule below.

| Additional Entity to be Included as Named Insured | Street Address, City, State, ZIP Code | Description of Operations | % of Ownership | Retroactive Date |
|---|---------------------------------------|---------------------------|----------------|------------------|
| | | | | |
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Coverage Underwriting/Eligibility Questions

Does the applicant have or is the applicant involved in any of the following?

Medical Devices

- | | | |
|--|---|---|
| Cold Therapy Devices | Gynological Ablation Devices | Power Morcellators for Gynecological Use |
| Concussion/Sport Safety and Testing | Heat Therapy Devices | Prosthetic/Orthotic Fitters |
| Contraceptive Devices | Home Medical Alert Monitoring Devices | Re-usable Warming/Cooling Devices |
| Any Cosmetic or Medical Devices Used for Cosmetic Procedures | Infusion Pumps for Pain Management | Robotic Surgery Devices |
| Discontinued Products for Safety/ Recall | IVC Filter | Synthetic Mesh Used for Gynecological or Urologic |
| Duodenoscopes | Lab-based Testing Services (CLIA, Genetic, General Patient/Athletics) | Weight Loss Devices |
| Food Testing Devices (Exception/ Referral) | Medical Staff Providing Direct Patient Care | |

Pharmaceuticals, Vitamins or Nutraceuticals

- | | | |
|---|--|--|
| Contraceptive or Birth Control Medication | Energy Drinks | Specified Nutraceutical ingredients (Aristolochia, Kava, Ephedrine, Ephedra, Usnea, Usnic Acid, Yohinbe) |
| Compounding Drugs | Medical Staff Providing Direct Patient Care | |
| Discontinued Products for Safety/ Recall | Pharmaceutical or Dietary Supplements Sold for Agriculture | |

If the applicant sponsors clinical trials, are they involved with any of the following?

| | | |
|---|----------------------------------|-------------------|
| Breast, Buttocks, Facial and/or Pectoral Implants | Gene and/or Stem Therapy | Pediatrics |
| Blood and/or Blood Products | Live Virus Vaccine Studies | Pregnant Women |
| Clinical Trials Where No-Fault Coverage Exists | Minor Enrollees | Prisoners |
| Contraceptive Devices or Medications | Nursing Mothers | None of the Above |
| | Obesity and/or Weight Loss Drugs | |

Does the applicant require the use of a Master Service Agreement (MSA) or contract/purchase orders for engagements with current and any future business partners?

Yes No

Complete only if requesting Professional Liability.

Contract Analysis – Identify provisions in the applicant’s service agreements.

Check all that apply

| | | |
|--|---|--|
| All Duties and Responsibilities of Each Party | Force Majeure (Extends to any and all Events Outside Applicant’s Control) | Hold Harmless Agreements/ Indemnifications |
| Arbitration Clause | Formal Customer Complaint Procedure | Limitation of Consequential Damages |
| Attorney Review of all Contracts and Agreements Including Changes Prior to use | Formal Payment Dispute Procedure | Limitation of Liabilities |
| Choice of Law or Jurisdiction | Guarantees | Warranty Disclaimers |

Revenue

Projected Domestic Revenue _____

Projected Foreign Revenue _____

Policy Underwriting Questions

General

Medical Devices

| | | | |
|--|-----|-----|-----|
| Does the applicant provide use and safety training of the products manufactured? | Yes | No | N/A |
| Does the applicant subcontract use and safety training of the products manufactured? | Yes | No | N/A |
| Is the subcontractor’s manufacturing facility FDA registered? | Yes | No | N/A |
| Are the applicant’s products or components manufactured outside of the US? | | Yes | No |
| If yes, list the countries _____ | | | |
| Are any products sold as components for other products? | | Yes | No |
| If yes, explain and provide end-product details _____ | | | |

Regulatory

Has the applicant had a recent FDA inspection in the last 12 months which resulted in 483s and/or any open 483s from the past?

If yes, attach copy. 

Have there been any of the following?

| | | |
|--|-----|----|
| Adverse Event Reporting (AERs) | Yes | No |
| Medical Device Reporting (MDRs), Warning Letters | Yes | No |
| Advisory Memorandums, Complaints, Regulatory Violations/Investigations | Yes | No |
| Domestic or International Agency, Federal Drug Administration (FDA) | Yes | No |
| Investigations filed to any products in the last 12 months | Yes | No |

If yes, provide details.

Have any clinical trials been discontinued or suspended due to safety reasons? Yes No

If yes, provide details.

Risk Management

Quality control program(s)

Check all that the applicant has in place.

- | | |
|------------------------------------|--|
| Loss Prevention Program | Client Complaint Resolution Procedures |
| Quality Management Control Program | Records Retention Program |
| Regulatory Affairs | |

Pharmaceuticals/Nutraceuticals/Vitamin Manufacturing

Does the applicant provide nutritional products for consumption by the livestock industry? Yes No N/A

Are any of the applicant's ingredients derived from animals? Yes No N/A

If yes, please list the animal source(s) _____

Does the applicant manufacture or distribute weight loss or body building supplements or medications? Yes No

Manufacturing Schedule

Describe all current, previous and new products planned for the next 12 months.

If products exceed five, submit a schedule with the application. 

| Product Description | Current, Previous or New Product | Intended Use/Application | Year Product Discontinued |
|---------------------|----------------------------------|--------------------------|---------------------------|
| | | | |
| | | | |
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| | | | |

Professional Service(s) Schedule

Describe all current, previous and new products planned for the next 12 months.

Complete if your risk provides any professional services.

| Professional Service Description | % of Total Revenue Derived from Professional Service |
|----------------------------------|--|
| | |
| | |
| | |
| | |

Clinical Trial(s) Schedule

Describe all current, previous and new clinical trials planned for the next 12 months.

Attach copy of protocol and consent form. 

| Clinical Trial Protocol Name and Description | Clinical Trial Product Category | Clinical Trial Protocol Number | Projected Test Participants for Policy Period | Total Past Test Participants | Phase | Trial Country |
|--|---------------------------------|--------------------------------|---|------------------------------|-------|---------------|
| | | | | | | |
| | | | | | | |
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Clinical Trial Sponsors

Are patient recruitment materials reviewed by risk management and legal counsel? Yes No N/A

If no, to what extent do you grant authority to individual entities or employees to amend recruitment materials?

Are standard operating procedures (SOPs) reviewed annually? Yes No N/A

Does credentialing of investigators include evaluation for having been disciplined, sanctioned or debarred from completing clinical trial work by a sponsor, CRO or federal government department or agency? Yes No N/A

Is the IRB accredited by the Association for the Accreditation of Human Research Protection Programs? Yes No N/A

Are financial disclosures (research staff) incorporated in the informed consent documents and process? Yes No N/A

Is the informed consent fifth-to-eighth-grade reading level and easily understood by a layperson? Yes No N/A

Professional Service(s) Schedule

Select Coverage(s) Needed

Products Liability

Professional Liability

Products Liability Limits

Each Claim Limit \$1,000,000 \$2,000,000 \$3,000,000 \$4,000,000 \$5,000,000 \$6,000,000 \$7,000,000

 \$8,000,000 \$9,000,000 \$10,000,000

Each Claim Deductible \$5,000 \$10,000 \$15,000 \$25,000 \$50,000 \$75,000 \$100,000

Aggregate Limit \$1,000,000 \$2,000,000 \$3,000,000 \$4,000,000 \$5,000,000 \$6,000,000 \$7,000,000

 \$8,000,000 \$9,000,000 \$10,000,000

Aggregate Deductible Unlimited (No Aggregate) \$5,000 \$10,000 \$15,000 \$25,000 \$50,000 \$75,000

 \$100,000 \$250,000 \$500,000 Other _____

Products Liability Retroactive Date _____

Medical Expenses

Each Person Limit \$1,000 \$5,000 \$10,000 \$25,000

Aggregate Limit \$5,000 \$10,000 \$25,000

Product Recall/Withdrawal (Class 1 Product Recall only – \$25,000 limit automatically included)

Optional Sublimit Excluded \$50,000 \$100,000 \$250,000

Coinsurance (%) 10% 20%

Aggregate Deductible \$10,000 \$15,000 \$25,000 \$50,000 \$100,000 \$150,000

Terrorism

Terrorism Coverage (Select if coverage is desired)

If Terrorism is rejected, TRIA Rejection form must be completed at end of application.

Professional Liability

Each Claim Limit \$1,000,000 \$2,000,000 \$3,000,000 \$4,000,000 \$5,000,000 \$6,000,000

 \$7,000,000 \$8,000,000 \$9,000,000 \$10,000,000

Each Claim Deductible \$5,000 \$10,000 \$15,000 \$25,000 \$50,000 \$75,000 \$100,000

Aggregate Limit \$1,000,000 \$2,000,000 \$3,000,000 \$4,000,000 \$5,000,000 \$6,000,000

 \$7,000,000 \$8,000,000 \$9,000,000 \$10,000,000

Aggregate Deductible Unlimited (No Aggregate) \$5,000 \$10,000 \$15,000 \$25,000 \$50,000

 \$75,000 \$100,000 \$250,000 \$500,000 Other _____

Professional Liability Retroactive Date _____

Mitigation Expenses – Applies to both Products and Professional coverage if purchased together or separately (\$250,000 limit automatically included)

Optional Sublimit Excluded \$500,000 \$750,000 \$1,000,000

Coinsurance (%) 20% (only option)

Product Portfolio

Product Breakdown – Indicate sales/revenue for each product within the applicable category

Medical Devices **Yes** **N/A**

| Description | Manufacturing Sales/Revenue | Distribution Sales/Revenue (Sale of Other Entities' Branded Products) | Contract Manufacturing Organization (CMO) Sales/Revenue |
|------------------------------|-----------------------------|---|---|
| Agricultural Products | | | |
| Anesthesia Respiratory | | | |
| Blood/Plasma/Tissue Products | | | |
| Cardiac | | | |
| Devices – Imaging | | | |
| Devices – Medical | | | |
| Devices – Ophthalmic | | | |
| Devices – Surgical | | | |
| Diagnostic Kits | | | |
| Devices – Therapy | | | |
| Drug Delivery | | | |
| Durable Medical Products | | | |
| Hospital Products/Supplies | | | |
| Imaging/Diagnostic Agents | | | |
| Implants – Active | | | |
| Implants – Orthopedic | | | |
| Implants – Ophthalmic | | | |
| Implants – Non-active | | | |
| Instruments – Analytical | | | |
| Instruments – Dental | | | |
| Laboratory Reagents | | | |
| Laser – Dermatology | | | |
| Laser – Ophthalmology | | | |
| Laser – Surgical | | | |
| Monitoring | | | |
| Other – Catheters | | | |
| Other – Dialysis | | | |
| Other – Infusion | | | |
| Veterinarian Products | | | |

Pharmaceuticals/Nutraceuticals **Yes** **N/A**

| Description | Manufacturing Sales/Revenue | Distribution Sales/Revenue (Sale of Other Entities' Branded Products) | Contract Manufacturing Organization (CMO) Sales/Revenue |
|---|-----------------------------|---|---|
| Active Pharmaceutical Ingredients | | | |
| Over the Counter (OTC) – Diet Aids | | | |
| Over the Counter (OTC) – Food Supplements | | | |
| Over the Counter (OTC) – Topicals | | | |
| Over the Counter (OTC) – Oral | | | |
| Over the Counter (OTC) – Vitamins | | | |
| Prescrip Topicals/Nutrition | | | |
| Prescrip Injectables/Oral – Biological | | | |
| Prescrip Injectables/Oral – Branded | | | |
| Prescrip Injectables/Oral – Generic | | | |
| Vaccines – DNA | | | |
| Vaccines – Killed Virus | | | |
| Vaccines – Live Virus | | | |
| Veterinarian Products | | | |

Blood/Plasma/Tissue Products **Yes** **N/A**

| Description | Manufacturing Sales/Revenue | Distribution Sales/Revenue (Sale of Other Entities' Branded Products) | Contract Manufacturing Organization (CMO) Sales/Revenue |
|------------------------------|-----------------------------|---|---|
| Blood/Plasma/Tissue Products | | | |

Complete section below ONLY if applicant's operations include the exposures.

Tissue Processors

Donor Screening and Tissue Procurement/Recovery

| | | |
|---|-----|----|
| Does the applicant perform the tissue procurement? | Yes | No |
| Does the applicant use a contracted recovery organization for tissue procurement? | Yes | No |
| Does the applicant or contracted recovery organization's tissue donor physical assessment form include recommendations from the most recent American Association of Tissue Banks (AATB) Guidance Document Tissue Donor Physical Assessment Form? | Yes | No |
| Does the applicant or contracted recovery organization follow the most recent AATB Guidance Document on Prevention of Contamination and Cross-Contamination At Recovery: Practices & Culture Results? | Yes | No |
| Does the applicant or contracted recovery agency use a Clinical Laboratory Improvement Act approved laboratory for the following testing: HIV-1, HIV-2, Hepatitis B and Hepatitis C? | Yes | No |
| Does the applicant or contracted recovery agency review the medical and social history of the donor, family and significant other? | Yes | No |
| Does the applicant or contracted recovery agency review the donor medical record? | Yes | No |
| Does the informed consent process include recommendations from the following: | Yes | No |
| <ul style="list-style-type: none"> • Model Elements of Informed Consent for Organ and Tissue Donation • Joint Statement of AATB Association of Organ Procurement Organizations • Eye Bank Association of America | | |

Donor Approval

| | | |
|--|-----|----|
| Is there an initial inspection of tissue utilizing acceptance and rejection criteria? | Yes | No |
| Is a medical director required to conduct the review for donor approval? | Yes | No |
| Does review for donor approval include the following: | Yes | No |
| <ul style="list-style-type: none"> • Physical assessment form • Medical, social and sexual history inquiry • Medical history and medical records • Infectious disease serological testing • Disease screening for infections, adverse conditions and risk factors such as malignancies • Coroner and autopsy reports, if applicable • Informed consent document | | |
| Is tissue ever released for processing prior to the medical director signing the donor record indicating release approval? | Yes | No |

Tissue Processing and Sterilization

| | | |
|--|-----|----|
| Are steps to remove and deactivate any foreign agents performed by heat, chemicals, dehydration or a combination of these? | Yes | No |
| Are validation studies, including viruses, bacteria and fungi completed to ensure that tissue processing is effective? | Yes | No |
| Is tissue ever pooled from more than one donor? | Yes | No |
| Is tissue stored at temperatures required by the FDA and the AATB? | Yes | No |
| Are there alarms and back-up power sources for freezers/coolers? | Yes | No |
| Is there a plan for preventive maintenance and calibration of equipment? | Yes | No |
| Is your organization utilizing proprietary technology for tissue processing and sterilization? | Yes | No |
| Is your organization utilizing a contracted company for tissue processing and sterilization? | Yes | No |
| If yes, please attach a copy of the contract. | | |

Tissue Tracking and Labeling

| | | |
|--|-----|----|
| Is there a donor/recipient tracking system? | Yes | No |
| Is each HCT/P (Human cells, tissues, and cellular and tissue-based products) labeled with a distinct alphanumeric identification code relating to all records pertaining to the donor? | Yes | No |

The undersigned authorized officer of the applicant knows of no other relevant facts which might affect the Company’s judgment when considering this renewal application and warrants that the statements herein are true, and it is agreed that this renewal application shall be the basis of the renewal contract and shall be deemed incorporated therein should the Company evidence its acceptance of this renewal application by issuance of a renewal policy. It is agreed that this renewal application shall be on file with the Company and that it shall be deemed to be attached to and made part of the renewal policy, if issued, as if physically attached to the renewal policy.

| | |
|------------|-------|
| Signature | Title |
| Print Name | Date |

Fraud Warnings

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 MAY BE SUBJECT TO CIVIL FINES AND CRIMINAL PENALTIES

For DC residents only

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 applicant.

For FL residents only

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.

For LA residents only

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.

For ME residents only

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.

For NY residents only

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 or incomplete information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and may be subject to civil fines and criminal penalties and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.

For OK residents only

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.

For PA residents only

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.

For PR residents only

Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.'

For TN residents only

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 or incomplete information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and may be subject to civil fines and criminal penalties. Penalties include imprisonment, fines and denial of insurance benefits.

For VT residents only

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 or incomplete information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which may be a crime and may be subject to civil fines and criminal penalties.

For WA residents only

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 or incomplete information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and may be subject to civil fines and criminal penalties. Penalties include imprisonment, fines and denial of insurance benefits.

“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.” 48.135.080. Required statement on all insurance applications and claim forms

No later than six months after July 1, 2006, or when the insurer has used all its existing paper application and claim forms which were in its possession on July 1, 2006, whichever is later, all applications for insurance, and all claim forms regardless of the form of transmission provided and required by an insurer or required by law as condition of payment of a claim, must contain a statement, permanently affixed to the application or claim form, that clearly states in substance the following:

“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.”