| JAMES RIVER INSURANCE | **James River Insurance Company and its Subsidiaries**<br>6641 West Broad Street, Suite 300<br>Richmond, VA 23230 | **Products Application**<br>**LIFE SCIENCES Division**<br>Email to LS@jamesriverins.com |
|---|---|---|

**APPLICANT'S INSTRUCTIONS:**

1. Answer all questions completely. Please attach extra sheets as required. Incomplete or illegible applications may be discarded.
2. Application must be signed and dated by the owner, partner, or officer not earlier than 90 days before the proposed effective date of coverage.
3. Please read the statements at the end of this application carefully. Thank you!

**Additional information required for this submission:**

- 5 year loss runs currently valued
- Copies of product catalogue, brochures, and literature

## SECTION I – GENERAL INFORMATION

| | | |
|---|---|---|
| Applicant name: | | |
| DBA: | | |
| Address: | | |
| City: | State: | Zip: |
| Phone: | Website: | |
| Years in business under current management: | Date established: | |
| Inspection contact name and information: | | |

Type of enterprise: ☐ Corporation ☐ Individual ☐ Partnership ☐ Proprietorship ☐ LLC ☐ Non-profit ☐ For profit ☐ Joint venture ☐ Government entity ☐ Other:

Description of operations:

List of subsidiaries and their operations:

List any additional offices and provide locations:

Have any of the principals engaged in this or similar enterprises under a different name? ☐ Yes ☐ No

If "Yes", please list entity and operations:

Provide business financial information for the last five (5) years and estimates for the next year:

| Year | Domestic sales | Foreign sales | Payroll | # of employees |
|---|---|---|---|---|
| Next year | | | | |
| Last year | | | | |
| 2nd year prior | | | | |
| 3rd year prior | | | | |
| 4th year prior | | | | |
| 5th year prior | | | | |

## SECTION II – OPERATIONS

1. Describe applicant's products, services, and the number of years each product or service has been offered. *(Attach additional pages, if needed.)*

| Product description | Years in market | Estimated product life | % of gross sales | Applicant is a/an M \| W \| R \| I \| MR | Products sold to M \| W \| R \| C \| O | Does applicant install \| repair |
|---|---|---|---|---|---|---|
| | | | % | | | |
| | | | % | | | |
| | | | % | | | |
| | | | % | | | |

M = Manufacturer R = Retailer MR = Manufacturer's representative W = Wholesaler I = Importer C = Consumer direct
O = Other, describe:

2. Describe applicant's revenues derived from the following types of products and operations *(percentages should add up to 100%)*:

| Source of revenue by product type | % of sales | Product description |
|---|---|---|
| Medical devices | % | |
| Diagnostics | % | |
| Proprietary/patent pharmaceuticals | % | |
| Generic pharmaceuticals | % | |
| Nutraceuticals or dietary supplements | % | |
| Other *(describe)*: | % | |
| **TOTAL** | 0 % | |

| Source of revenue by operation | % of sales | Product description |
|---|---|---|
| Contract research | % | |
| Contract manufacturing | % | |
| Distribution | % | |
| Equipment rentals/leasing | % | |
| Repair/installation/service | % | |
| Other *(describe)*: | % | |
| **TOTAL** | 0 % | |

3. Will any new products be introduced in the next 12 months? ☐ Yes ☐ No
   If "Yes", please explain:

4. Have any products been discontinued during the past 10 years? ☐ Yes ☐ No
   If "Yes", please explain which products were discontinued and the reason for each:

5. Have any new products been acquired by merger or acquisition? ☐ Yes ☐ No
   If "Yes", please explain:

6. Did applicant assume liability for these products? ☐ Yes ☐ No
   If "Yes", please explain:

 

## SECTION III – NUTRACEUTICALS AND PHARMACEUTICALS

*(Only complete this section if the applicant will have revenues derived from pharmaceutical or nutraceutical products or operations. If none, please mark as N/A.)*

1. Describe applicant's revenues from the following types of products *(percentages should add up to 100%)*:

| Product | % of sales | Product | % of sales |
|---|---|---|---|
| Vaccines | % | Imaging/diagnostic agents | % |
| Hormones and steroids | % | Nutrapharmaceuticals | % |
| Birth control or fertility treatments | % | Vitamin/food supplements | % |
| Anti-depressants | % | Body building products | % |
| Weight reduction | % | Diet aids | % |
| Erectile dysfunction | % | Male/sexual enhancement | % |
| Addictive substances | % | Other *(please explain)*: | % |

2. Nutraceutical Ingredients: describe any exposures applicant has to the following ingredients. If applicant wishes to obtain coverage for any of the ingredients listed below, supply dosage and revenue information for the ingredient. *(This must be provided in order for us to consider whether we will provide coverage for the ingredient.)*

| Ingredient | Dosage | Application | % of sales |
|---|---|---|---|
| Bitter Orange/Citrus Aurantium | | ☐ Topical ☐ Injestible | % |
| Colloidal Silver | | ☐ Topical ☐ Injestible | % |
| Comfrey | | ☐ Topical ☐ Injestible | % |
| Kava | | ☐ Topical ☐ Injestible | % |
| Lobelia | | ☐ Topical ☐ Injestible | % |
| Magnolia | | ☐ Topical ☐ Injestible | % |
| Organ/Glandular Extracts | | ☐ Topical ☐ Injestible | % |
| Skullcap | | ☐ Topical ☐ Injestible | % |
| Stephania | | ☐ Topical ☐ Injestible | % |
| Willow Bark | | ☐ Topical ☐ Injestible | % |
| Yohimbe | | ☐ Topical ☐ Injestible | % |

3. Do any of applicant's products carry the USP (United States Pharmacopeia) certification mark or NF (National Formulary) seal on the label? ☐ Yes ☐ No

4. Does applicant promote any products for use in children? ☐ Yes ☐ No

5. Do any of applicant's product labels include health claims? ☐ Yes ☐ No
   If "Yes",
   a. Which ones?

   b. How have these claims been substantiated?

6. Do nutraceutical and/or dietary supplement product labels clearly state that the FDA has not evaluated them? ☐ Yes ☐ No

7. Do applicant's product labels clearly state all necessary warnings concerning safety information including any known side effects and contraindications? ☐ Yes ☐ No

8. Do any of applicant's products have similar names that might reflect that are intended for the same use as a FDA approved drug? ☐ Yes ☐ No

9. Have any of applicant's products ever had an active ingredient that would be defined as a "drug" by the FDA? ☐ Yes ☐ No
   If "Yes", what are they?

 

10. Identify any product requiring the addition of a black box or other significant safety warning to exiting labeling or instruction manuals within the last five (5) years:

11. Indicate any product or service *(past or present)* that has been involved with any certified or attempted class action or multi-district litigation:

## SECTION IV – MEDICAL DEVICES

1. Complete this section if applicant will have revenues from medical devices.

| Product | % of sales | Product | % of sales |
|---|---|---|---|
| Cardiac | % | Dialysis | % |
| Anesthesia/respiratory | % | Infusion | % |
| Implants – active | % | Diagnostic devices | % |
| Implants – non-active | % | Diagnostic kits | % |
| Lasers | % | Analytical instruments | % |
| Surgical instruments | % | Durable medical equipment | % |
| Dental instruments | % | Hospital products/supplies | % |
| Monitoring devices or life support equipment | % | Devices that contain silicone | % |
| Imaging devices | % | Devices that contain latex | % |
| Therapy/rehab equipment | % | Other *(please explain)*: | % |

| Class of device | % of sales |
|---|---|
| Class I | % |
| Class II | % |
| Class III | % |
| TOTAL *(percentages should add up to 100%)* | 0 **%** |

2. Describe any devices that contain latex or silicone:

## SECTION V – PROCESSING AND QUALITY CONTROL

1. Does applicant design and manufacture the complete product? ☐ Yes ☐ No
   If "No", describe products or components purchased:

2. Do any products, ingredients, or components originate from outside the United States? ☐ Yes ☐ No
   If "Yes":
   a. Specify the country(ies) of origin:

   b. Does applicant import these products or components directly? ☐ Yes ☐ No
   c. Are imported products and components tested for contamination and verification that they match what was ordered? ☐ Yes ☐ No

 

3. Do others manufacture, assemble, or package products under applicant's name or label? ☐ Yes ☐ No
   If "Yes", please provide the name(s) and address(es) of the contract manufacturers:

4. Does applicant obtain COIs evidencing products liability insurance coverage from each manufacturer and supplier based in the United States? ☐ Yes ☐ No

5. Is applicant named as an additional insured vendor on each manufacturer's/supplier's product liability insurance? ☐ Yes ☐ No

6. Does applicant have written quality control and testing procedures in place? ☐ Yes ☐ No
   If "Yes",
   a. How long are quality control and testing records kept?
   b. Has applicant obtained any of the following quality registration(s)/certification(s)?
      *(Check all that apply):* ☐ ISO 9000 ☐ ISO 9001 ☐ ISO 13485 ☐ QS 9000

7. Can applicant identify their product(s) from those of competitors? ☐ Yes ☐ No
   If "Yes":
   a. Describe how applicant's products are distinguished from those of competitors.

   b. Do applicant's records indicate the date of sale and purchaser of products? ☐ Yes ☐ No

8. Does applicant maintain complete inventory records of shipments and/or deliveries to consignees? ☐ Yes ☐ No
   If "Yes", are serial and/or batch numbers shown on the finished product and on shipment invoices? ☐ Yes ☐ No

9. Does applicant have a specific program to withdraw known or suspected defective products from the market? ☐ Yes ☐ No

10. Has applicant recalled or considered recalling any product(s)? ☐ Yes ☐ No
    If "Yes", please explain:

11. Provide the date of applicant's last FDA inspection?
    Was a FDA 483 form issued? ☐ Yes ☐ No
    If "Yes", please attach the 483 form, applicant's response(s), and FDA acceptance of response(s) as adequate.

## SECTION VI – CLINICAL TRIALS

1. Please list active clinical trials that are currently being sponsored or will be sponsored during the upcoming policy term.

| Product | # of participants | Indication | Trial phase | Trial location |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

2. How many clinical trials has applicant sponsored in the last three (3) years?

3. How many participants were enrolled in these trials during the last three (3) years?

4. Have any trials been discontinued for safety reasons? ☐ Yes ☐ No
   If "Yes", please explain:

5. Does applicant have formalized clinical trial suspension policy in place? ☐ Yes ☐ No

6. Have any clinical investigators been cited for regulatory violations in connection with applicant's trials? ☐ Yes ☐ No
   If "Yes", please explain:

7. What is the targeted reading grade level for applicant's informed consents?

8. Does applicant require clinical investigators to test participants on their understanding of the informed consent document? ☐ Yes ☐ No

 

| | | |
|---|---|---|
| 9. | Does applicant ever act as both trial sponsor and clinical investigator? | ☐ Yes ☐ No |
| 10. | Does applicant provide material/product, or both, for clinical trials that they do not sponsor? | ☐ Yes ☐ No |

## SECTION VII – PRIOR INSURANCE & CLAIMS HISTORY

1. Please provide insurance information for the past three (3) years.

| Carrier | Limits | Deductible | Retro date | Premium | Exposure base or policy rate |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

2. In the last five (5) years, have any adverse events have been reported to applicant and/or the FDA concerning applicant's products? ☐ Yes ☐ No
   If "Yes", please state number of events and provide details for each *(attach a separate page if more space is needed)*:

3. Has any claim been made against any person(s) or organization(s) to be covered under this insurance during the last five (5) years? ☐ Yes ☐ No
   If "Yes", please provide five (5) year loss history for all claims below and attach a description for any loss greater than $10,000:

| Year | # of claims | Total paid | Total reserves | Total incurred | Valuation date |
|---|---|---|---|---|---|
| | | | | $ 0 | |
| | | | | $ 0 | |
| | | | | $ 0 | |
| | | | | $ 0 | |
| | | | | $ 0 | |

## SECTION VIII – SIGNATURE, CONSENT AND AGREEMENT

This Application is the basis for coverage; therefore, any incorrect or incomplete statements or answers could nullify coverage. Completion of this form neither binds coverage nor guarantees that a policy will be issued. *(Not applicable in North Carolina)*

I hereby request that my application for insurance coverage be submitted for consideration to the company shown in this application. Accordingly, I authorize and direct any person or organization whatsoever to release and furnish to that company any and all information requested which may relate to my insurability.

I hereby indicate that the aforementioned statements and answers are correct and complete. I further understand that an incorrect or incomplete statement or answer could void my protection.

I hereby consent to the review by the company shown in this application of any incidents or occurrences likely to result in malpractice allegation or claim. I agree to cooperate in the review of claims and incidents which apply to the coverage requested.

Where applicable, I hereby consent to the review of my application by the committees appointed by my county or state professional association / society. I agree to cooperate with these committees.

**COPY OF NOTICE OF INFORMATION PRACTICES (PRIVACY) HAS BEEN GIVEN TO THE APPLICANT.**

*(Not required in all states, contact your agent or broker for your state's requirements.)*

Personal information about you, including information from a credit or other investigative report, may be collected from persons other than you in connection with this application for insurance and subsequent amendments and renewals. Such information as well as other personal and privileged information collected by us or our agents may in certain circumstances be disclosed to third parties without your authorization. Credit scoring information may be used to help determine either your eligibility for insurance or the premium you will be charged. We may use a third party in connection with the development of your score. You may have the right to review your personal information in our files and request correction of any inaccuracies. You may also have the right to request in writing that we consider extraordinary life circumstances in connection with the development of your credit score. These rights may be limited in some states. Please contact your agent or broker to learn how these rights may apply in your state or for instructions on how to submit a request to us for a more detailed description of your rights and our practices regarding personal information. *(Not applicable in AZ, CA, DE, KS, MA, MN, ND, NY, OR, VA, or WV. Specific ACORD 38s are available for applications in these states.)*

**NOTICE TO APPLICANT**

The coverage applied for is solely as stated in the policy. If policy is issued on a "CLAIMS MADE" or "CLAIMS MADE AND REPORTED" basis, it provides coverage only for those claims that are first made against the insured during the policy period unless the extended reporting period option is exercised in accordance with the terms of the policy. If issued on an "OCCURRENCE" basis, the policy provides coverage only for those occurrences

 

that take place during the policy period.

The Insurer will rely upon this application and all such attachments in issuing the policy. If the information in this application or any attachment materially changes between the date this application is signed and the effective date of the policy, the Applicant will promptly notify the Insurer, who may modify or withdraw any outstanding quotation or agreement to bind coverage.

**FRAUD STATEMENTS**

**Applicable in AL, AR, DC, LA, MD, NM, RI and WV**

Any person who knowingly (or willfully)* presents a false or fraudulent claim for payment of a loss or benefit or 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. **Applies in MD Only.*

**Applicable in CO**

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.

**Applicable in FL and OK**

Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing false, incomplete, or misleading information is guilty of a felony (of the third degree)*. **Applies in FL Only.*

**Applicable in KS**

Any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

**Applicable in KY, NY, OH and PA**

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* (not to exceed five thousand dollars and the stated value of the claim for each such violation)*. **Applies in NY Only.*

**Applicable in ME, TN, VA and WA**

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. **Applies in ME Only.*

**Applicable in NJ**

Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

**Applicable in OR**

Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

☐ ***I have read the statements above, understand their meaning and agree.***

Applicant's signature:

Date:

Applicant's name:

Applicant's title:

 