

PHARMACEUTICAL PRODUCTS LIABILITY APPLICATION INSTRUCTIONS

- *Please answer every question fully, using extra sheets or exhibits as needed.*
- *Please be certain all attachments are included as detailed on page 14 or where otherwise required.*
- *To assist you, here are some important definitions:*



DEFINITIONS

<u>Multi-Source:</u>	Products whose active ingredient(s) are past the initial patent period , including generic, branded off-patent, private label, or patented products when the active ingredient(s) are off-patent (such as a transdermal delivery system).
<u>Patented:</u>	Products in the initial patent period.
<u>Ethical:</u>	Products available only by doctor's prescription .
<u>OTC:</u>	Over the Counter, or products that do not require doctor's prescriptions, including vitamins.
<u>Distributed:</u>	Products manufactured by others and distributed by you, either repacked by you or distributed as received.
<u>Non-Pharmaceuticals:</u>	Other products that are not pharmaceutical products <i>per se</i> , such as cosmetic, food products, medical equipment, dental supplies, veterinary products, bulk chemicals, etc.



A. J. Renner & Associates

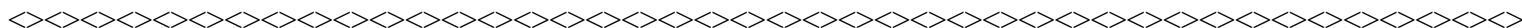
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APPLICATION FOR PHARMACEUTICAL PRODUCTS LIABILITY INSURANCE



This application must be completed in its entirety, then signed and dated by an officer of the company. If the answer to any question is "none" or "not applicable", please so answer. Please use extra sheets if necessary to completely answer each question.

1. Name _____

2. Address _____

Telephone () _____ Insurance Contact _____

3. Individual, co-partnership corporation? _____

4. How many years have you been in business under the present name? _____

Have you ever engaged in this or similar enterprises under a different name? _____

If so, please set forth details. _____

5. Please provide a brief description of your operations. _____

6A. If you are a subsidiary of another corporation, please give parent corporation's name and relationship. _____

6B. Please list all subsidiaries of the company for which coverage is desired. _____

7A. Location from which products are manufactured: _____

7B. Location from which products are distributed: _____

8. Show sales for the last five (5) years including the current policy year.

POLICY YEAR (MOST CURRENT FIRST)	NET SALES (MILLION) *
/ / - / /	\$
/ / - / /	\$
/ / - / /	\$
/ / - / /	\$
/ / - / /	\$
/ / - / /	\$

* "NET SALES" MEANS GROSS SALES LESS RETURNS, DISCOUNTS AND CHARGE BACKS.

9. Please provide estimated sales from the coming 12-month period (or upcoming insurance period), broken down as follows:

I. Ethical Products			
a.	Multi-Source Manufactured by you	\$ _____	
b.	Multi-Source Distributed by you	\$ _____	_____ % Repacked
a.	Patented Manufactured by you	\$ _____	
b.	Patented Distributed by you	\$ _____	_____ % Repacked
II. Over the Counter Products			
a.	Manufactured by you	\$ _____	
b.	Distributed by you	\$ _____	_____ % Repacked
III. Non Pharmaceutical Products			
a.	Manufactured by you	\$ _____	
b.	Distributed by you	\$ _____	
TOTAL ESTIMATED SALES		\$ _____	

What percentage of your total estimated sales are foreign (outside of the United States, its territories and possessions, Puerto Rico and Canada)? _____ %

Please attach a separate sheet providing a breakdown of non-pharmaceutical product sales either manufactured or distributed by you by product line, i.e., cosmetics, medical equipment, dental supplies, bulk chemicals, veterinary products, etc.

Please list below your top 10 products and provide estimated sales for each:

Product	Estimated Sales
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

9B. Confirm that the applicant/insured has never manufactured or distributed Phentermine, Fenfluramine and/or Dexfenfluramine. _____

9C. Confirm if the applicant/insured has ever/or currently manufactures or distributes a product containing Phenylpropanolamine Hydrochloride (PPA)? If yes, please provide details. _____

10. Do you manufacture the complete product? _____ If not, what component parts are purchased by you?

11. Do you compound the ingredients and package the same? _____

12. Describe your quality control procedures. _____

13. Do you maintain samples of products in your quality control procedure? _____

If so, how long are samples retained? _____

14. Has your product ever been removed from the market by any government authority?_____

If so, please set forth in detail._____

15. Have you recalled any of your products for any reason?_____

If so, please set forth in detail. Be sure to identify voluntary versus involuntary and class recalls.

16. Do you maintain complete inventory records reflecting shipment and/or delivery to consignee and are serial and/or batch numbers reflected on the finished product and on shipment invoices?_____

17. Have any products been discontinued?_____ If so, give full and complete descriptions, reason and number of years discontinued.

18. Please provide complete details of new products you expect to sell in the next twelve (12) months.

CLAIMS EXPERIENCE

19A. Please provide amounts of all product liability claims in the past ten (10) years, including amounts paid, expenses and amounts reserved. Please also attach loss runs issued by your present/prior insurance carriers for the past ten years. Insurance Carrier Documented Loss Experience is required by underwriters prior to binding.

YEAR	TOTAL PAID	TOTAL EXPENSES	TOTAL RESERVES	TOTAL INCURRED
	\$	\$	\$	\$
	\$	\$	\$	\$
	\$	\$	\$	\$
	\$	\$	\$	\$
	\$	\$	\$	\$
	\$	\$	\$	\$

19B. Please provide full details of any claim paid or reserved in excess of \$10,000.00. _____

19C. Please provide details of any suit brought against you. _____

20. Are you aware of any incidents or circumstances arising out of your products that could give rise to or would likely result in a claim against you? _____ If yes, please provide details.

21. For all products distributed by you, please provide the name of the manufacturer. Specify which products bear your name or label. _____

22. Do you give or obtain hold harmless or indemnity agreements to/from your dealers or suppliers? _____

If yes, please attach copies.

23. Have you been in violation of any consumer product safety act or any other federal or local legislation? _____

If yes, provide details. _____

24. What companies have previously provided Product Liability Insurance for you?

POLICY TERM DATES	COMPANY NAME	LIMITS OF COVERAGE	DEDUCTIBLE OR SIR	PREMIUM	CLAIMS MADE OR OCCURRENCE	RETROACTIVE DATE (IF ANY)
			DED or SIR	\$	CM or O	
			DED or SIR	\$	CM or O	
			DED or SIR	\$	CM or O	
			DED or SIR	\$	CM or O	
			DED or SIR	\$	CM or O	

25. Has any insurance company canceled or refused to renew your product liability insurance? _____
 If yes, why? _____

26. What is your estimated payroll for the next 12 months? _____

27A. What limit of liability do you desire? _____

27B. What is the effective date of the proposed insurance? _____

28. What self insured retention are you prepared to carry? _____

29. **Please attach any additional information** about your company that you feel would assist underwriters in evaluating your company and your product liability exposures.

30. Please list professional associations of which you are a member: _____

GEN PHARM RISK MANAGEMENT

The following questions to the Gen Pharm application are mandatory. They are designed to provide additional information that will enable Underwriters to better assess the Insureds exposures.

These questions are important and will enhance understanding of risk management procedures in many areas. Please answer them fully.

Products

Do you have any past, present, or planned association with any of the following:

Product Name	Annual Sales	% Manufacturing	% Distribution	Name of Mfg. for the Distributed Products
Acitretin				
Alatrofloxacin				
Alosetron				
Amiodarone				
Androsteredione				
* Anti Depressant / SSRIs				
Apomorphine				
Aristolchic Acid				
* ADHD/ADD Products				
Bromfenac (Duract)				
Bromocriptine				
Butanediol				
Butorphanol				
Chaparral				
Chomper				
Cisapride				
Citrus Aurantium (bitter orange)				
Comfrey				
Creatine				
Dehydroepiandrosterone				
Dieters' Tea				
Diethylstilbestrol				
Ephedrine				
Estazolam				
Gamma Butyrolactone				
Gamma Hydroxybutyric Acid				
Germander				

Germanuim				
Grepafloracin				
* HRTs				
Indinavire				
* Isotretinoin				
Itraconazole				
Jin Bu Huan				
Kava				
L-Tryptophan				
Latex				
Leflunomide				
Magnolia				
Metronidazole				
Mutagens				
Nefazadone				
Oral Contraceptives				
Oxycodone				
Phenylpropanolamine (PPA)				
Phentermine				
Pseudoephedrine				
Psychotropic Drugs Products				
Sildenafil, Vardenafil, Tadalafil				
St. Johns' Wort				
Stephanra				
* Statins				
Sumatriptan				
Teratogens				
Thalidomide				
Theophylline				
Thiazolidinediones				
Thimersol				
Tiractricol				
Tretinoin				
Triax Metabolic Accelerator				
Vaccines				
Weight Reduction Products				
Willow Bark				
Yohimbe				

* Provide details of your Defense Strategy for these products.

Questions for Distributors as respects the above products:

1. As a distributor will the company be doing any re-packaging or re-labeling of the product? ____ Yes ____ No
If yes please provide details:
2. Will the company be named as an additional insured under manufacturers' insurance policies? ____ Yes ____ No

2. What percentage of the company's advertising budget is allocated to Direct to Consumer advertising? What type of DTC advertising is used? Please provide examples of any Direct to Consumer advertising materials. Do you sell directly to physicians? If so, what are the top 3 most expensive perks you give to physicians?

3. Do you conduct annual regulatory & product liability training with your sales and marketing staff?

Clinical Trials and Bio Studies

If you are involved with human clinical trials and/or bio studies please answer the following questions:

Do you anticipate any clinical trials and/or bio studies in the next 12 months? _____

If "yes" please provide the following information:

Bio Studies

1. Number of studies anticipated: _____
2. Number of subjects anticipated: _____
3. Do any of the anticipated studies involve products for which you hold the initial patent? _____.
If "yes" please fully describe by attachment.
4. Are all studies conducted by independent third party investigators? _____
If "no" please describe by attachment.

Clinical Trials

1. Number of studies anticipated: _____
2. Number of subjects anticipated: _____
3. Are all studies conducted by independent third party investigators? _____
If "no" please describe by attachment.

4. Please complete the Human Clinical Trial Schedule attached and provide copies of all Protocols including the Informed Consent Document.

Additional Questions

1. Have any bio-studies or clinical trials involving the company's products been suspended or discontinued due to safety reasons in the last 5 years? *(If yes, please provide details).*
2. Do you allow any of the following: Clinical Investigator's enrolling their own patients, enrollment bonuses, contacting patients directly via patient databases, or patient referral fees?
3. Have any of your Clinical Investigator's been cited for regulatory violations involving your trial activities? *(If yes, provide details).*
4. Have you had any evidence of serious regulatory non-compliance or fraud by your Clinical Investigator's and their staff in the past 5 years? *(If yes, provide details).*
5. Do you put all your informed consent documents through well-established readability testing, for example, the Flesch-Kincaid Grade level Scoring?
6. Are you in compliance with the FDA requirements concerning financial disclosures?
7. Do you incorporate financial disclosures in your informed consent documents or process?
8. What has been the maximum compensation you have offered trial participants?

9. Do you anticipate any Clinical Trials or Bio Studies outside of North America for which separate specific insurance is required? *(If yes, provide details).*

IMPORTANT - PLEASE ATTACH THE FOLLOWING ITEMS:

- A. Current Audited Financial Statement
- B. Provide a listing of all products by chemical name and estimated sales for each. This listing does not need to include products that have already been stated earlier in this application; this is to be in addition of what has already been stated earlier in this application.
- C. Provide brochures and any direct to consumer advertising materials used to market your products.
- D. Copy of your most recent inspection by the FDA and/or any other authorities, your response to such reports and remedial action plans that resulted from such inspections or investigations.
- E. Loss runs for the past **ten (10) years** of similar written documentation of past claims experience supporting information summarized in question 19.
- F. Terrorism Questionnaire Completed.

All questions in this application have been answered to the best of my knowledge, and I know of no other facts that are relevant or would affect underwriter's evaluation of the company and its product liability exposures.

BY _____

TITLE _____

DATE _____