

## Medical and Pharmaceutical Products Application

If this application is accepted by Steadfast, the insurance will be written on a claims-made basis and will only apply to written claims first made against the insured during the policy period. No coverage will exist for claims first made against the insured after the end of the policy period unless the extended discovery period applies. No coverage will exist for any claim, the basis of which is bodily injury or property damage which occurs prior to the retroactive date shown in the declarations page of the policy. Leave no spaces blank.

Please be certain all attachments are included as requested or where required.

### Important 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.
<u>Patented</u>	Products in the initial patent period.
<u>Ethical</u>	Products available only by a doctor's prescription.
<u>OTC</u>	Over the Counter, or products that do not require a doctor's prescription, including vitamins.
<u>Distributed</u>	Products manufactured by others and distributed by the applicant, either repacked by the applicant or distributed as received.
<u>Non Pharmaceutical</u>	Other products that are not pharmaceutical products such as cosmetics, food products, medical equipment, dental supplies, veterinary products, bulk chemicals.

1. Name of Applicant: \_\_\_\_\_

2. Address: \_\_\_\_\_

Web site: \_\_\_\_\_

Insurance Contact \_\_\_\_\_

Telephone number \_\_\_\_\_

E-mail address \_\_\_\_\_

3.  Individual  Co-partnership  Corporation  \_\_\_\_\_

4. How many years has the applicant been in business under the present name? \_\_\_\_\_

Has the applicant ever engaged in this or similar enterprises under a different name? If so, please provide full details:

\_\_\_\_\_

5. If the applicant is a subsidiary of another corporation, identify the parent corporation: \_\_\_\_\_

Does any of the insurance purchased by the above described parent corporation(s) afford any coverage to you? If so, please detail: \_\_\_\_\_

Please list all subsidiaries of the company for which coverage is desired. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

6. Location of each premises at which applicant's products [described in question 9(A)] are manufactured:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Location of each premises from which applicant's products [described in questions 9(A) and (B)] are distributed:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Confirm that the applicant/insured has never manufactured or distributed Phentermine, Fenfluramine and/or Dexfenfluramine. \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

7. List dollar value of gross sales of applicant's products described in questions 9(A) and 9(B) for the past 5 calendar years including a dollar estimate of gross sales for the upcoming calendar year:

<u>YEAR</u>	<u>GROSS RECEIPTS</u>
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

8. What is the applicant's annual payroll: \_\_\_\_\_

9. (A) Please give a complete description of all the products manufactured by the applicant. Include annual gross receipts and years on the market for each product:

<u>PRODUCT</u>	<u>RECEIPTS</u>	<u>YEARS ON MARKET</u>
_____	_____	_____
_____	_____	_____

(B) Describe completely all products distributed by the applicant (but manufactured by others) which are not listed in 9(A). Include annual gross receipts and years on the market for each product:

<u>PRODUCT</u>	<u>RECEIPTS</u>	<u>YEARS ON MARKET</u>
_____	_____	_____
_____	_____	_____

10. (A) If the applicant's product line includes the manufacture or distribution of pharmaceuticals, please provide estimated sales for the coming 12-month period, broken down as follows:

1. Ethical Products:

- a. Multi-Source Manufactured by you      \$ \_\_\_\_\_
- b. Multi-Source Distributed by you      \$ \_\_\_\_\_      \_\_\_\_\_ % Repacked
- c. Patented Manufactured by you      \$ \_\_\_\_\_
- d. Patented Distributed by you      \$ \_\_\_\_\_      \_\_\_\_\_ % Repacked

2. Over the Counter Products

- a. Manufactured by you \$ \_\_\_\_\_
- b. Distributed by you \$ \_\_\_\_\_ % Repacked

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

(B) Are any of the applicant's products designated Schedule C II or C III? \_\_\_\_\_  
If yes, please provide the name of product, C II or C III designation and the annual sales.

\_\_\_\_\_  
\_\_\_\_\_

Are any of the applicant's products designated category "D" or "X" as respects fetal risk? \_\_\_\_\_  
If yes, please provide the name of product, "D" or "X" designation and the annual sales.

\_\_\_\_\_  
\_\_\_\_\_

11. (A) Is the applicant presently manufacturing or distributing products which are being used in clinical research on human subjects? If yes, please identify each product by name, the manufacturer, trial phase, and number of human subjects participating:

\_\_\_\_\_  
\_\_\_\_\_

Do any of the anticipated trials or studies involve compounds for which you are holding the **initial** patent? If yes, please fully describe each such trial or study. \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(B) With respect to each product which is a medical device intended for human use, state whether the device is classified as Class I, II, or III under U.S. Code Title 21, Sec. 360c, as amended:

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(C) Are all anticipated trials or studies conducted by independent third-party investigators? If so, please describe. \_\_\_\_\_

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12. Does the applicant's product line include the manufacture or distribution of any vaccine intended for human or animal consumption? If so, please identify:

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13. With respect to each product manufactured by the applicant and listed under questions 9, 10, 11 and 12 above, does the applicant manufacture the complete product?

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With respect to each product not so manufactured, specify which component parts are purchased by the applicant:

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14. Does the applicant compound the ingredients of any product and package same? \_\_\_\_\_

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15. Does the applicant maintain quality control procedures? \_\_\_\_\_

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16. Does the applicant maintain samples of products involved in applicant's control procedures? If so, how long are samples retained?

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17. Are all the products presently manufactured or distributed by the applicant approved for sale in the United States by the United States Food & Drug Administration. If not, please identify each such product and state the reason(s) why they are not approved for sale.

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18. Indicate the distribution percentage (based on gross receipts) of the applicant's products by geographic region:

West Coast \_\_\_\_\_ East Coast \_\_\_\_\_ Midwest \_\_\_\_\_  
Southwest \_\_\_\_\_ Southeast \_\_\_\_\_ Foreign \_\_\_\_\_

19. With respect to each product described in 9(B), specify each product which bears the applicant's name or label:

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20. Specify which products the applicant distributes in original containers for direct consumption by the consumer:

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21. What products does the applicant distribute in bulk to wholesalers? \_\_\_\_\_

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22. What materials or products handled by the applicant are poisonous, either by themselves or in a combination with other materials?

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23. Is the applicant affiliated in any manner with any of the applicant's suppliers or distributors? If so, please state the nature of such affiliation:

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24. Does the applicant distribute any product which has been manufactured and/or packaged outside of the United States or its possessions? If so, please describe each such product, % of its gross receipts and country of origin:

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25. Has any of the applicant's products ever been removed from the market by any government authority? If so, please indicate the circumstance(s) and product(s):

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26. Has the applicant voluntarily or involuntarily recalled any of its products for any reason? If so, please specify for each: Date of recall, product(s) involved, U.S. Food and Drug Administration Class I, II or III, and reason for recall:

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Was the recall(s) completed? \_\_\_\_\_

27. Does the applicant have a formal recall plan? If so, please describe: \_\_\_\_\_

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28. Have any of the applicant's products ever been subject to any inquiry or investigation by any government agency concerning its efficiency, adequacy of labeling, hazardous contents and/or safety? If so, please describe in detail:

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29. (A) Does the applicant maintain complete inventory records, including details of shipment? \_\_\_\_\_

(B) Are serial and/or batch numbers identified on the finished product and on shipment invoices? \_\_\_\_\_

30. Has the applicant been cited for any violation of the Consumer Product Safety Act or any other federal, state or local law? If so, describe each citation and detail disposition on each:

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31. Does the applicant provide any maintenance or repair services for any of the products it sells or distributes? If so, please describe and provide annual payroll figures for these services over the past three years:

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32. Does the applicant have any product which is leased, either on a short or long term basis? If so, please list each such product:

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33. Have any of the products manufactured by the applicant been discontinued? If so, give a full and complete description of each such product(s), the number of years since the product was last manufactured, and the reason(s) for discontinuing the product:

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34. Please list any unusual side effects of your products: \_\_\_\_\_

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35. Are any of the applicant's products sold sterile? \_\_\_\_\_

If so, does the applicant sterilize or contract out? \_\_\_\_\_

If contracted out, does the applicant receive a hold harmless agreement from each contractor? \_\_\_\_\_

36. Are any products manufactured or distributed by the applicant accompanied by written statements, instructions or brochures? \_\_\_\_\_ If yes, please attach copies.

37. What limits of Products Liability Insurance do you desire:

\$ \_\_\_\_\_ Each Claim

\$ \_\_\_\_\_ Annual Aggregate

38. What self-insured retention or deductible is the applicant prepared to carry? \$ \_\_\_\_\_

39. Does the applicant give or obtain hold harmless or indemnity agreements from its dealers or suppliers? If so, please attach a copy of each.

40. Does the applicant plan to manufacture any product which it intends to market within the next six months from the date of this application? If so, please give a brief description of each product:

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41. Please provide loss data for the past seven years, including amounts paid, details of losses, reserves and any claims of incidents reported to the applicant:

<u>YEAR</u>	<u># OF CLAIMS</u>	<u>AMOUNT PAID</u>	<u>AMOUNT RESERVED</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

42. Please provide full details of any suit brought against you. \_\_\_\_\_

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43. Is the applicant aware of any incidents or circumstances involving or arising out of the manufacturing/distributing of any of the products herein above referred to that is likely to result in a claim(s) against the applicant? If so, please provide details:

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44. For the past five years identify each insurer which provided Products Liability Insurance to the applicant.

Policy Term	Company	Limits	Ded./SIR	Premium	CM or Occ.	Retro Date (if any)

45. Has any insurance company ever refused to issue or canceled Products Liability Insurance provided to the applicant? If so, please explain:

\_\_\_\_\_

\_\_\_\_\_

46. With respect to the applicant's sales folders, guarantees of performance, containers, labels, precautions, restrictions, manuals of instruction, and similar materials; are these materials reviewed and approved for use by the applicant's legal counsel prior to distribution by the applicant? \_\_\_\_\_

47. Please attach the following items:

- A. Current Audited Financial Statement
- B. Copies of all brochures, written statements, instructions, labels that accompany your products.
- C. 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.

48. Name and phone number of insurance contact: \_\_\_\_\_

Dated at \_\_\_\_\_ this \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_\_

Name of applicant \_\_\_\_\_

Signed by \_\_\_\_\_

Title \_\_\_\_\_