

# LIFE SCIENCES / BIOTECHNOLOGY / BIOMEDICAL

## PROPOSAL

### Public & Products Liability & Clinical Trials

**This form must be signed by the insured/proposer or a person employed and/or authorised by the insured/proposer.**

When completing the form, if more space is required, please supply additional details as an attachment.

**ALL QUESTIONS MUST BE ANSWERED IN FULL**

**1. Insured/proposer details**

Name of insured/proposer:

Trading name: (if applicable)

Tax Registered Business?  Yes  No ABN / ACN & all other licence numbers:

Address of all premises to be covered by this insurance:		<input type="checkbox"/> Owned		<input type="checkbox"/> Leased
		<input type="checkbox"/> Owned		<input type="checkbox"/> Leased
		<input type="checkbox"/> Owned		<input type="checkbox"/> Leased
		<input type="checkbox"/> Owned		<input type="checkbox"/> Leased

Website:  NOTE: Your Duty of Disclosure requirements are not relieved by providing the details of your website address

Date insured commenced trading:

Full Business Description:

Has any insurer ever refused to renew, decline, cancel or impose special terms on any insurance held by you?  Yes, please provide details below  No

Who is your current insurer?

**2. Period of insurance** From:  To:  at 4pm

### 3. Limit of indemnity required

 \$5m

 \$10m

 \$20m

### 4. Claims History

Have any goods or products been recalled during the past 10 years?

 Yes

 No

If Yes, please provide details:

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Have you had any claims made against you in the last 5 years?

 Yes

 No

Date	Brief Description	Paid *	Outstanding *	Excess	Insurer

\* Please put gross amount before deduction of any policy excess.

### 5. Turnover details

Actual turnover for the <b>last 12 months</b>	Estimated turnover for the <b>next 12 months</b>
\$	\$

Please provide a percentage split of your Estimated Turnover for the **next 12 months** by geographical area:

ACT	NSW	NT	QLD	SA	TAS	VIC	WA	Overseas
%	%	%	%	%	%	%	%	%

Estimated annual turnover split for the **next 12 months** between:

a) Own manufacture (where you hold the Product Licence)	\$
b) Where you hold the Product Licence but manufacture is contracted to third party	\$
c) Where you Contract Manufacture for third parties	\$
d) Wholesale (unaltered from manufacturers)	\$
e) Parallel import / repackaged or relabeled wholesale products	\$
f) Others, please specify how income is generated (and if appropriate, please provide specimen contracts:	\$

Of the estimated annual turnover split for the **next 12 months**, please state estimated turnover to:

	a) Own Manufacture	b) Product Licence Holder	c) Contract Manufacture	d) Whole-sale (unaltered)	e) Parallel Import	f) Others
Australia	\$	\$	\$	\$	\$	\$
New Zealand	\$	\$	\$	\$	\$	\$
USA/Canada	\$	\$	\$	\$	\$	\$
Rest Of The World	\$	\$	\$	\$	\$	\$

Are any exports sent directly to customers from manufacturers outside Australia?  Yes  No

If Yes, please advise territory/territories sent from:

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Is there a formal contract in place regarding Quality Control? Please provide details.

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## 6. Payroll details

Please advise the estimated annual wage roll including Directors, Partners & Principals):

	Actual figures for the last 12 months	Estimated figures for the next 12 months
Management, administrative & sales – retail	\$	\$
Warehousing/storage, service on-site	\$	\$
Installation, maintenance, service, repair or construction work conducted away from premises	\$	\$
Other, please specify:	\$	\$

No. of employees: Full time  Part time  Casual

## 7. Contractors / Sub Contractors / Labour Hire

Do you engage the use of Contractors / Sub Contractors?  Yes  No

If Yes, please provide details below.

Nature of work performed (please provide a split by activity performed) i.e. engaged contract driver to deliver product to customer on consignment basis. Labour only component \$25,000.	Actual payments for contract labour (contractors/sub contractors) for the last 12 months	Estimated payments for contract labour (contractors/ sub contractors)for the next 12 months
	\$	\$
	\$	\$
	\$	\$
	\$	\$

Do you engage the use of Labour Hire Employees?  Yes  No

If Yes, please provide details below.

Nature of work performed (please provide a split by activity performed) i.e. forklift driver \$100,000; production worker \$50,000, office administration \$25,000.	Actual payments for labour hire for the last 12 months	Estimated payments for labour hire for the next 12 months
	\$	\$
	\$	\$
	\$	\$
	\$	\$

Do you check to ensure that all Labour Hire Employees, Contractors and/or Sub-Contractors carry their own Public Liability and Workers Compensation insurances?  Yes  No

If Yes, please provide details of how this is checked, and how records are maintained.

Do you insist to be named either as Principal or as a joint insured in liability policies of Contractor/Sub-Contractors and do you obtain a Certificate of Currency of such insurance?  Yes  No

**8. Product Information:**

Description of Product	Manufactured (M) / Distributed (D)	Actual Turnover Over Last 12 Months	Estimated Turnover for the Next 12 Months
	<input type="checkbox"/> (M) <input type="checkbox"/> (D)	\$	\$
	<input type="checkbox"/> (M) <input type="checkbox"/> (D)	\$	\$
	<input type="checkbox"/> (M) <input type="checkbox"/> (D)	\$	\$
	<input type="checkbox"/> (M) <input type="checkbox"/> (D)	\$	\$
	<input type="checkbox"/> (M) <input type="checkbox"/> (D)	\$	\$
	<input type="checkbox"/> (M) <input type="checkbox"/> (D)	\$	\$

Please provide details of Australian manufacturers / Australian suppliers from where your products are sourced:

Australian Manufactured / Australian Sourced Products			
Name of manufacturer / supplier	Product Details	Address of manufacturer / supplier	Turnover (\$)
			\$
			\$
			\$
			\$

Have any goods, products or services that you have provided been discontinued during the past 10 years?  Yes  No

If Yes, please provide details:

Please provide details of all products that have been manufacturer, supplied or sourced from overseas:

Imported Products			
Name of manufacturer / supplier	Product Details	Country where Products are manufactured	Turnover (\$)
			\$
			\$
			\$
			\$

Are you required to modify, assemble, repackage or label any imported products?  Yes  No

If Yes, please provide details:

Does the manufacturer's / supplier's products liability policy provide cover for products exported to Australia?  Yes  No

If Yes, please provide details:

Are your interests noted on the manufacturer's / supplier's product liability policy as a vendor or distributor?  Yes  No

If Yes, please provide details:

Please provide details of all products that have been manufactured, supplied or sourced that you are exporting:

<b>Exported Products (NOTE: Please also complete Section 9 "USA/Canada" if you export to USA/Canada)</b>			
Name of company that product has been supplied	Product Details	Country where Products are exported to	Turnover (\$)
			\$
			\$
			\$
			\$

In each of the countries where your products are sold, do product labels and instructions comply with jurisdictional regulations and do your products comply with all relevant official standard or government regulations laid down in these countries?  Yes  No

If No, please provide details:

Are any new products likely to be marketed during the next 12 months?  Yes  No

If Yes, please provide details:

## 9. USA/Canada

Please answer these questions <b>ONLY</b> if you export to the USA/Canada	
a) Please provide a full description of all products exported.	<input style="width: 100%; height: 30px;" type="text"/>
b) How long have you been producing each product?	<input style="width: 100%; height: 30px;" type="text"/>
c) Do you comply with the State/Federal Laws applicable to each product?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d) Do you have any Power of Attorney or asset in USA/Canada?  If <u>Yes</u> , do they arrange separate insurance including Completed Operations/Products?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<p>e) Are you required to indemnify any vendors and/or distributors in USA/Canada?</p> <p>If <u>Yes</u>, please provide names and addresses.</p> <p>If <u>No</u>, do they maintain their own insurance for Completed Operations/Products? State limit if known.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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## 10. Quality Control

Do you work to or are your products required to be compliant with any Australian or International Standards or any other Industry standard or regulation?  Yes     No

If Yes, please provide details:

Do you have any quality control procedures in place?  Yes     No

If Yes, please provide details:

Does quality control involve the testing of a sample percentage of products?  Yes     No

If Yes, please state:

Percentage of products checked

Failure rate

## 11. Design/Specification

Please give full details and percentage of total turnover of products that are:

- a) Manufactured/supplied to own design/specification/formulation
- b) Manufactured/supplied to a design/specification/formulation laid down by a customer?

	%
	%
	100%

Do you have a separate design team?  Yes     No

If Yes, please provide details:

Describe the extent and type of tests and checks undertaken before products go into production.

## 12. Recall

Is it possible to trace the ultimate customer of individual products or batches in order to recall the products?  Yes  No

Please provide details:

Is there a formal procedure for emergency product recall?  Yes  No

Please provide details:

Has recall ever been necessary or been considered?  Yes  No

If Yes, please provide details:

Please give details of product lines discontinued because of incidence or injury or damage, or where potential hazards have been identified – stating when manufacture or supply ceased.

Describe the extent and type of tests and checks undertaken before products go into production.

## 13. Marketing

Are products labelled and supplied with clear instructions in the language of the country to which they are supplied?  Yes  No

Are product hazard warnings clearly shown on products, packaging and/or instruction manuals?  Yes  No

Do your legal and/or design departments have sight of all advertising materials, sales brochures, operating manuals etc to check for misleading statements?  Yes  No

Are your representatives warned against overstating usage or effectiveness of products?  Yes  No

If No to any of the above, please provide details:

## 14. Advice, Designs Or Specifications To Third Parties

Do you provide any advice, designs or specifications to third parties for a fee only  Yes  No that is NOT in connection with the supply of a Product?

If Yes, please provide details:

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## 15. Specified Pharmaceutical Products/Product Categories

The standard policy wording excludes “specified products” and “specified product categories” as defined below, or where applicable, any derivative, extract, adulated botanical or botanical derivative of a specified product or anything that contains or has the same or similar chemical formula, structure or function to a specified product.

Please check the relevant box(es) if you have any products/product categories that fall within these definitions.

Any product(s) that does/do not have the appropriate regulatory approval	<input type="checkbox"/>	L-tryptophan	<input type="checkbox"/>
Blood Borne Pathogens	<input type="checkbox"/>	LYMERix	<input type="checkbox"/>
Bisphosphonates	<input type="checkbox"/>	Metoclopramide	<input type="checkbox"/>
Bupropion	<input type="checkbox"/>	Paroxetine	<input type="checkbox"/>
<b>a)</b> Cerivastatin; <b>b)</b> the concomitant or combined use of two or more different products which contain: <b>i)</b> a Statin; and <b>ii)</b> a Fibrate. <b>c)</b> Rhabdomyolysis arising out of either <b>a)</b> or <b>b)</b> above	<input type="checkbox"/>	Pertussis Vaccine	<input type="checkbox"/>
Contraceptives (including birth control pills), fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy	<input type="checkbox"/>	Phenylpropanolamine (PPA)	<input type="checkbox"/>
Cox-2 Inhibitors	<input type="checkbox"/>	Prozac	<input type="checkbox"/>
Diethylstilbestrol or Stilbestrol or DES	<input type="checkbox"/>	Retinoic Acid	<input type="checkbox"/>
Ephedrine, Ma Huang, Pseudoephedrin, Chinese Ephedra, Mahuang Extract, Ephedra, Ephedra Sinica, Ephedra Extract, Ephedra Herb Powder or Eptonin	<input type="checkbox"/>	Rosiglitazone	<input type="checkbox"/>
Fluoxetine	<input type="checkbox"/>	Silicone – any product containing silicone which is in any form implanted or injected in the body	<input type="checkbox"/>
Fentanyl	<input type="checkbox"/>	Thimerosal or Thiomersal	<input type="checkbox"/>
Isotretinoin or Accutane	<input type="checkbox"/>	Thiazolidinediones	<input type="checkbox"/>
Kava or Kava Kava	<input type="checkbox"/>	Tobacco or any tobacco products (or ingredients thereof)	<input type="checkbox"/>
Latex and/or latex protein and/or latex derivatives and/or latex substances howsoever the latex, latex protein, latex derivatives or latex substances are named identified described or classified	<input type="checkbox"/>		



If you have checked any of the boxes in Section 15 on the previous page, please provide full details as follows:

Are products supplied on a Named Patient Basis only or in accordance with Special Licence(s) granted?  Yes  No

If Yes, please provide details of licence(s) held:

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If No, please provide the following details:

a) Product details enclosing Data Safety Sheets where possible	
b) If manufactured, to whose formula/specification?	
c) If marketed only, are rights of recourse maintained against manufacturers/suppliers?	
d) How long have you marketed or manufactured the products?	
h) Estimated annual turnover per specific product	
f) If exports involved, details of territories to be supplied with estimated turnover	

## 16. Premises

Have all manufacturing locations been inspected by TGA/FDA or other regulatory body/bodies?  Yes  No

If Yes, what was the date of the last inspection?

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Have you ever had a manufacturing licence withdrawn?  Yes  No

If Yes, please give details including remedies

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## 17. Hazardous Goods / Waste

Does your business create any waste?  Yes  No

If Yes, please provide details of waste and methods of disposal:

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Is your business subject to EPA or other regulations?  Yes  No

If Yes, please provide details:

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Please provide details of any Hazardous Goods that are stored at your premises.

Substance	Quantity	Storage Details	Use

## 18. Clinical Trials

Please answer these questions **ONLY** if you conduct clinical trials.

***In addition, please supply the Protocol and Informed Consent Form for each trial.***

Product	Number of subjects to be enrolled	Indications	Phase	Country/Countries Trials Are Conducted

Have there been any claims or serious adverse events for Clinical Trials in the past 5 years?  Yes  No

If Yes, please provide details:

## 19. Goods In Your Care, Custody & Control

Do you require cover for goods in your care, custody & control?  Yes  No

If Yes, please provide details of goods in your care, custody & control:

If Yes, please advise limit:

\$

## 20. Indemnities / Hold Harmless Agreements

Please provide details of any indemnities or "Hold Harmless" agreements given to other parties.

## 21. Sanctions

- (a) Do any of the your company/companies (including Subsidiary or if applicable joint venture) covered by this proposed insurance policy have a legal entity or propose to conduct business with an entity:-
- (i) that is registered in any Australian, UK, EU or US **SANCTIONED\*** country?  Yes  No
  - (ii) that is owned or controlled (>= 50% voting rights) directly or indirectly by a jurisdiction or any public authority within an Australian, UK, EU or US **SANCTIONED\*** country?  Yes  No
  - (iii) that is owned or controlled (>= 50% voting rights) directly or indirectly by any natural person resident in any Australian, UK, EU or US **SANCTIONED\*** country?  Yes  No
- (b) Do any of the your company/companies (including Subsidiary or if applicable joint venture) covered by this proposed insurance policy have a legal entity or propose to conduct business with an individual that appears on any Specially Designated Nationals and Blocked Persons List which would contravene Australian, UK, EU or US **SANCTIONS\*** ?  Yes  No

IF Yes to any of the above questions, please provide details:

\* Please refer to <http://www.dfat.gov.au/sanctions/> for details on **SANCTIONS**.

## 22. Declaration

### ***Your Duty of Disclosure***

You have a duty under the Insurance Contracts Act 1984 before you enter into a contract of general insurance with Newline Australia Insurance to disclose to Newline Australia every matter that you know, or could reasonably be expected to know, is relevant to Newline Australia's decision whether to accept the risk of the insurance and, if so, on what terms.

If you fail to answer all questions fully and accurately, Newline Australia may find cause to reduce or cancel the cover. This disclosure includes any renewal, extension, variation or the reinstatement of a contract of general insurance.

While completing this proposal, you will have provided us with some private information. We are committed to protecting your privacy in accordance with the Privacy Act 1988 (Commonwealth). We will only use this information for the purpose of the consideration of application for this Insurance or if required to do so by law. You are entitled to access your personal information and request any amendment, update or correction as deemed necessary.

**I declare that to the best of my knowledge and belief that the answers given above are the truth and that I have not withheld any information that is considered to be material to this proposed Insurance. I declare that my answers not given in my handwriting have been checked by me for their truth and accuracy.**

**Signature:**

*NOTE:*

*If this proposal has been completed electronically, please print out Section 22 (Declaration), sign in the box on the left, and send this page (either as a scan attachment or fax) together with the preceding pages.*

**Full Name:**

**Position Held:**

**Date:**