Pharmaceutical/Chemical and Allied Trades

PUBLIC AND PRODUCTS LIABILITY

NEW BUSINESS QUESTIONNAIRE

Public Liability - Losses Occurring
Products Liability - Claims Made

QUESTIONS	*ANSWERS*
Full Name (s) of all companies to be included:	
Address:	
Telephone No:	
When established:	
Exact Nature of Business:	
Website Address:	

PLEASE ATTACH PRODUCT LITERATURE, SPECIMEN BROCHURES, CONDITIONS OF SALE, SALES LITERATURE AND TECHNICAL INFORMATION AS APPROPRIATE.

Estimated annual turnover:

i)	Own Manufacture	£ .....
ii)	Wholesale	£ .....
iii)	Product Licence Holders where manufacture is contracted to third party	£ .....
iv)	Other (please describe)	£ .....

1. EXPORTS Please state estimated annual turnover to:	*Own Manufacture*	*Wholesale*	*Other*
i) USA	£.....	£.....	£.....
ii) Canada	£.....	£.....	£.....
iii) Other countries (please state countries)	£.....	£.....	£.....
	£.....	£.....	£.....
	£.....	£.....	£.....
Please state any exports sent direct from manufacturers outside the UK	£.....	£.....	£.....

PLEASE ANSWER ALL QUESTIONS FULLY OR WITH YES, NIL OR NONE (DASHES ARE UNACCEPTABLE).

2. Please answer this question ONLY if you export to the USA/Canada.	
(a) A full description of all products exported and approximate percentage of total applicable to each product.	
(b) For how long have you been producing each product?	
(c) For how long have you been exporting these products to the USA/Canada and to which States in particular?	
(d) Do you comply with the State/Federal Laws applicable to each product?	

	(e) Means of export to USA/Canada i.e.:- (i) direct subsidiary in USA/Canada (ii) incorporated in part of machinery or commodity sold direct by other manufacturers (iii) sold in country of origin to selling Agent in USA/Canada (f) Do you have any Power of Attorney or assets in the USA/Canada? (g) Full details of all contractual terms, warranties, including all oral or written undertakings given by or to USA/Canada sellers or suppliers. (h) Is the USA/Canada seller or supplier insured for products liability including imported goods? State limit if known.	
3.	(a) do you have any representation outside the UK? If YES, please give full details. (b) Are any visits made or is work undertaken outside the UK? If YES, please give full details.	
4.	IMPORTS If you import products please state from which countries obtained and approximately percentage of total turnover against each.	
5.	Do products comply with all relevant:- a) British Standard, Industry and Trade Standards or Government Safety Licensing Regulations or equivalent local legislation. b) Official Standard or Government Regulations laid down in countries to which Products are exported?	
6.	DESIGN/SPECIFICATION a) Please give full details and percentage of total turnover of products that are: i) manufactured/supplied to own design/specification/formulation ii) manufactured/supplied to a design/specification/formulation laid down by a customer	

b) Do you have a separate design team?

If YES, what are their technical qualifications and practical experience?

c) Describe extent and type of tests and checks undertaken before Product goes into production.

7. QUALITY CONTROL

a) Do you have a written statement relating to Quality Control?

If YES, please provide a copy or indicate its main features.

How often is it reviewed?

b) Do you have a Quality Control Organisation?

If YES: (i) who has overall responsibility?

(ii) can control be overridden by Design, Production or Marketing Personnel?

c) Does Quality Control involve:-

(i) specified minimum standards of procedures?

(ii) the testing of a sample percentage of goods?

If Yes, please state:

a) percentage of products checked

b) failure rate.

d) Are sampling inspections made on:-

i) incoming raw materials?

ii) incoming parts?

e) i) What is the procedure for dealing with customers complaints?

ii) Are all complaints referred to appropriate Departments for consideration and rectification of fault (if any)?

iii) Are records of complaints retained?

8.	Is it possible to trace the ultimate customer of individual products or batches in order to recall the products?	
9.	Is there an emergency product recall procedure?	
10.	Has recall every been necessary or been considered? If YES, please give details.	
11.	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.	
12.	MARKETING a) Are products labelled and supplied with clear instructions in the language of the country to which they are supplied? b) Are products hazard warnings clearly shown on Products, Packaging and/or Instruction Manuals? c) Do your Legal and/or Design Departments have sight of all advertising material, sales brochures, operating manuals etc. To check for misleading statements? d) Are your Representatives warned against overstating usage or effectiveness of Products?	
13.	RECORDS a) Do you maintain an adequate system of records which would enable identification of:- i) source of Product/raw materials/component parts purchased? ii) source of design of Products manufactured iii) Quality control and testing procedures effective at the time of design and/or manufacture? iv) Research undertaken to minimise risk to health and safety. b) In respect of (a), (i), (ii), and (iv) above, how long are such records kept?	(i) ..... (ii) ..... (iii) ..... (iv) .....

14.	a)	Please state whether you currently manufacture or market or have in the past manufactured or marketing any of the following:	
	(i)	Blood Borne Pathogens	(i) .....
	(ii)	Breast Implants	(ii)
	(iii)	Buproprion	(iii)
	(iv)	Canthaxanthin	(iv) .....
	(v)	Cerivastatine	(v) .....
	(vi)	Contraceptives (including birth control pills) fertility drugs and products specifically designed and marketed for use during and in connection with pregnancy	(vi)
	(vii)	Danthron	(vii) .....
	(viii)	Debendox	(viii) .....
	(ix)	Dexfenfluramine Fenfluramine or Phentermine	(ix) .....
	(x)	Dicyclomine when give to children under 4 years of age	(x)
	(xi)	Diethylstilbestrol	(xi) .....
	(xii)	Dioxins	(xii)
	(xiii)	Ephedrine Ma Huang Chinese Ephedra Mahuang Extract Ephedra Ephedra Sinica Ephedra Extract Ephedra Herb Powder Epitonin or any derivative thereof	(xiii) .....
	(xiv)	Fluoxetine	(xiv)
	(xv)	Germanium	(xv) .....
	(xvi)	Halogenated 8 & Hydroxy Quinoline	(xvi) .....
	(xvii)	Methylphenidate	(xvii)
	(xviii)	Pertussis Vaccine	(xv iii) .....
	(xix)	Phenylpropanolamine (PPA)	(xix) .....
	(xx)	Primodos/Amenorone Forte	(xx) ……..
	(xxi)	Propulsid	(xxi) ……
	(xxii)	Prozac	(xxii) .....
	(xxiii)	Retinoic Acid	(xxiii) .....
	(xxiv)	Skin whitening and lightening agents.	(xxiv) .....
	(xxv)	Swine-Flu Vaccine	(xxv) ……..
	(xxvi)	Thalidomide	(xxvi) ……..
	(xxvii)	Tretinoin	(xxvii) ……..
	(xxviii)	Tryptophan	(xxviii) ……..
	(xxix)	any Products causing or failing to cure or alleviate any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever it may be named. Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).	(xxix) ……

UNLESS IT IS SPECIFICALLY AGREED WITH UNDERWRITERS COVER PROVIDED MAY EXCLUDE ANY LIABILITY ARISING OUT OF THE FOREGOING.

14.	b)	If you have answered YES to any of questions	

14(a) from previous page please give full details as follows: a) Product details and whether manufactured or marketed only. (NB Please enclose data sheet, if available). b) If manufactured, to whose formula/specification. c) If marketed only, full details if normal rights of recourse are no maintained. d) How long have you marketed or manufactured. e) Estimated annual turnover:- i) manufactured ii) marketed f) If exports involved details of territories to be supplied and estimated turnover.	 £ £
15. Do you manufacture or supply any products on an 'off' licence or Named Patient basis? If so please advise:- a) The nature of licence held granting permission b) Nature of products supplied off licence c) Estimated Annual Turnover: i) Marketed ii) Manufactured d) If exports are involved please supply full details of territories to be supplied and the estimated turnover	 £ £
16. PREMISES (please detail all locations):- Address: Description: e.g. office, factory etc.	
17. If you are engaged in the manufacture, wholesale or distribution of chemicals please provide full details (including plan if possible) or surrounding property.	

18. Will any radioactive substance or other sources of ionising radiation be handled or used:	

If YES, please give full details.	
19. Has any Insurer ever:- a) Declined your proposal for Public &/or Products Liability insurance b) refused your renewal for Public &/or Products Liability insurance c) Terminated your Insurance for Public &/or Products Liability . If YES, please give full details	
20. Have any incidents occurred during the last five years resulting, or alleged to have resulted in death, injury or disease to third parties or damage to their property? If YES, please give details:	

Date	Brief Details of Incident whether or not an insurance claim has been made	Paid Amount	Insurers Outstanding Reserve

21. Are you aware of any circumstances which might give rise to a claim If YES, please give details	
22. Please state if your existing cover for Products Liability is on a "Claims made" basis or a "Losses occurring" basis. If on a "Claim made" basis please state how many years the cover has been on this basis.	

COVER WILL EXCLUDE LIABILITY ASSUMED UNDER AGREEMENT THAT WOULD NOT HAVE ATTACHED IN THE ABSENCE OF SUCH AGREEMENT IN CONNECTION WITH PRODUCTS SUPPLIED.

IF COVER IS REQUIRED FOR CLINICAL TRIALS A SUPPLEMENTARY QUESTIONNAIRE WILL NEED TO BE COMPLETED.

23 Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent:

£1,000,000 .....

£2,000,000 .....

£3,000,000 .....

£4,000,000 .....

£5,000,000 .....

If higher please state: £ .....

I/We declare that to the best of my/our knowledge and belief the above statements are true and complete and will form part of the contract between me/us and the Underwriters.

Name and position of person completing this Questionnaire:-

Name: .....

Position: .....

Signed: .....

Date:

IMPORTANT:

1. The answers to this form preferably should be typed, or alternatively completed in ink. The form must be signed by a Partner or Director of the Firm.

2. All questions must be answered. If not, no quotation will be given. The completion and signature of this form does not bind the Proposer or Underwriter to complete a contract of insurance.

3. If you have insufficient space to complete any of your answers please continue on your headed paper and attach it to this form.

4. It is your duty to disclose all material facts to Insurers. A material fact is one that is likely to influence a prudent Insurer's judgement and acceptance of your proposal. If you are in any doubt as to whether or not certain information is material then it should be disclosed.