Cosmetics

2018 Proposal form

Important notice:

1. This is a proposal for a contract of insurance, in which 'proposer' or 'you/your' means the individual, company, partnership, trust, charity, establishment or association proposing for cover

2. This proposal must be completed in ink, signed and dated. All questions must be answered to enable a quotation to be given but completion does not bind you or Underwriters to enter into any contract of insurance. If space is insufficient to answer any question fully, please attach a signed continuation sheet. You should retain a copy of the completed proposal (and of any other supporting information) for future reference.

3. You are recommended to request a specimen copy of the proposed policy or certificate from your insurance broker and to consider carefully the terms, conditions, limitations and exclusions applicable to the cover. The proposed insurance covers only those losses which arise from certain events discovered or claims made against the Assured during the period of insurance, as specified in the policy or certificate.

4. Part A – General information is mandatory and must be completed by all proposers
   Part B – Property and business interruption is optional and should only be completed if cover is required
   Part C – Declarations is mandatory and must be completed by all proposers

PART A – General information (mandatory)

1 General information

(i) Name of Proposer	
(ii) Address	
(iii) Website address	
(iv) Year established	

(v) Employment Reference Number for each entity to be included in this agreement

Entity	ERN
a.	
b.	
c.	

2 Business description	

3 Please note we **do not** provide cover for any registered offices, subsidiaries or employees within the European Union (excluding the United Kingdom of Great Britain and Northern Ireland and its territories).

Please confirm whether this is sufficient for your requirements Yes ☐ No ☐

4 Income

(i) Please provide a split in your projected annual revenue for the forthcoming period of insurance between the following geographical areas:

a. United Kingdom £
b. United States of America £
c. Elsewhere £

(ii) What percentage of your activities relate to the research and development of your own product %

(iii) To help us understand your business, please provide a further split in your projected annual revenue by type of activity and field of specialism.

	1) Own product manufacture &/or sale	2) Contract manufacture for third parties	3) Distribution or retail of third party branded product
a. Medicinal products	£	£	£
b. Medical devices	£	£	£
c. Laboratory equipment	£	£	£
d. Food supplement	£	£	£
e. Total diet replacement	£	£	£
f. Food for special medical purposes	£	£	£
g. Cosmetics	£	£	£
h. Cosmetic devices	£	£	£
i. Other	£	£	£
Total	£	£	£

(iv) Do you provide professional services for a fee or where a fee would normally be charged Yes ☐ No☐

a. Please describe those services

b. What fee income do you derive from these services £

5 Do you have any past, present or planned future products classified as or include any of the substances listed in appendix 1 Yes ☐ No☐

If Yes please indicate which are applicable on Appendix 1

6 Do you have any past, present or planned future products classified as or include any of the product categories listed in appendix 2 Yes ☐ No☐

If Yes please indicate which are applicable on Appendix 2

7 Are any of your past, present or planned future products classified as, or include;

(i) an in vitro diagnostic listed under annex II of Directive 98/79/EC Yes ☐ No☐

(ii) a class IIa or IIb invasive medical device for long term use (more than 30 days) Yes ☐ No☐

(iii) class III medical device Yes ☐ No☐

(iv) a custom made medical device Yes ☐ No☐

(v) radioactive material Yes ☐ No☐

(vi) an orthotic device with functional electric stimulation (FES) Yes ☐ No☐

(vii) devices used for cleaning or disinfecting medical instruments or devices Yes ☐ No☐

8 Are any of your past, present or planned future products classified as, or include;

(i) a generic drug, biosimilar or advanced therapy medicinal product Yes ☐ No☐

(ii) food supplements

a. that make claims of having properties of preventing or treating disease in human beings Yes ☐ No☐
b. for animals Yes ☐ No☐
c. specifically designed for children, pre natal or post natal care Yes ☐ No☐
d. for sexual dysfunction Yes ☐ No☐

(iii) a sports nutritional supplement Yes ☐ No☐

(iv) cosmetics containing a classified Carcinogenic, Mutagenic or Reprotoxic (CMR) substance Yes ☐ No☐

(v) hair dyes, skin lightening products, sunless tanning products, nail care products or chemical peels Yes ☐ No☐

(vi) tattoo equipment and accessories / tattoo ink / black or natural henna (lawsone (2-hydroxy-1,4-naphthoquinone)) Yes ☐ No☐

(vii) nanomaterial (1nm-100nm) Yes ☐ No☐

(viii) sunscreen Yes ☐ No☐

(ix) cosmetic skin rejuvenation devices Yes ☐ No☐

(x) cosmetic laser systems, intense pulsed light (IPL) equipment or light emitting diode (LED) devices — Yes ☐ No☐

(xi) muscle stimulation/toning devices — Yes ☐ No☐

9 Do any of your activities include

(i) contract manufacturing of products where you deviate from specifications provided by your customer including but not limited to use of approved raw materials, ingredients, parts and methods. — Yes ☐ No☐

(ii) the operation of an inpatient facility — Yes ☐ No☐

(iii) testing for paternity, drug or substance abuse, HIV, TSE or Hep C, environmental, marine or agricultural pollution. — Yes ☐ No☐

(iv) acting as a European Authorised Representative for a non-European manufacturer — Yes ☐ No☐

(v) importing in to the territory a finished product from outside the European Economic Area — Yes ☐ No☐

(vi) the distribution or retail of a third party branded product where you are NOT indemnified by the manufacturer for liability for damages arising from a defect in that product. — Yes ☐ No☐

(vii) subcontracting the design, manufacture, assembly, packaging or installation of your product to a third party organisation — Yes ☐ No☐

(viii) the personal fitting of orthopaedic devices — Yes ☐ No☐

(ix) sterilisation, configuration, repair, adaptation, translation of, or writing of instructions or relabeling (other than delivery notes) of a third party product — Yes ☐ No☐

(x) sponsoring clinical trials — Yes ☐ No☐

(xi) selling products or services over the internet to territories outside the European Economic Area — Yes ☐ No☐

(xii) laboratories NOT working to ISO15189 or compliant with EU 2004/9/EC and EU 2004/10/EC — Yes ☐ No☐

(xiii) working with Group 3 or Group 4 biological agents — Yes ☐ No☐

10 Compliance

(i) are you aware of any pervasive off label use, misuse or deviation from instructions for use of any of your products. — Yes ☐ No☐

(ii) have any of your past or present products or services been provided by you without the required license or registration from the relevant regulatory body in the territory in which they are to be distributed e.g. marketing authorisation or CE mark. — Yes ☐ No☐

(iii) are any of your products, subject to the European Black Triangle Scheme, a prohibited or restricted herbal ingredient, a Traditional Chinese Medicine or Herbal Medicine not granted a traditional herbal registration (THR) — Yes ☐ No☐

(iv) are you aware of any circumstance where

(a) your product or service is not lawfully allowed to be sold or performed in any of Your chosen markets — Yes ☐ No☐

(b) there is any connection between you and/or your business, your product or service and a country or person subject to trade sanctions — Yes ☐ No☐

or embargoes asserted by the United Kingdom (UK), European Union (EU), United Nations (UN) or United States of America (USA)

(c) your back office systems have not prevented or will not prevent sales to these territories? Yes ☐ No ☐

11 Have you ever

(i) been subject to an enforcement notice, warning letter or other punitive action by a relevant regulatory body Yes ☐ No ☐

(ii) been subject to corrective or preventative action by a regulatory body in respect of good manufacturing practice (cGMP) Yes ☐ No ☐

(iii) manufactured, sold or supplied any products subject to an unexpected or unintended serious side effect, adverse drug reaction, medical device adverse incident or serious undesirable effect Yes ☐ No ☐

(iv) manufactured, sold or supplied any products withdrawn or discontinued due to a safety, efficacy or performance reason; initiated by you or a relevant regulatory body Yes ☐ No ☐

12 Do you always obtain qualified legal advice in all the countries to which You are selling or plan to sell your product or service to ensure compliance with all relevant legislation, regulation and local customs? Yes ☐ No ☐

13 Do you ever agree to

(i) unilateral hold harmless agreements Yes ☐ No ☐
(ii) waiver of any of your rights and remedies Yes ☐ No ☐
(iii) any form of indemnification to anyone other than the parties to the contract Yes ☐ No ☐

14 Can you confirm you have a written contract with all your customers, vendors, partner companies and suppliers Yes ☐ No ☐

15 Where a written contract exists, can you confirm it includes

(i) a force majeure clause Yes ☐ No ☐
(ii) a consequential loss exclusion Yes ☐ No ☐
(iii) a reasonable limitation of your liability Yes ☐ No ☐
(iv) a detailed description of the obligations of each party Yes ☐ No ☐
(v) a description of the standard of care that you will provide Yes ☐ No ☐
(vi) a termination clause Yes ☐ No ☐
(vii) dispute resolution / mediation procedure Yes ☐ No ☐
(viii) a clause making the contract subject to the exclusive jurisdiction of English and Welsh or Scottish courts? Yes ☐ No ☐

16 Can you confirm

(i) all changes to contracts are documented and signed off by all parties Yes ☐ No ☐

(ii) the terms and conditions of your contract satisfy the "test of reasonableness" under the Unfair Contract Terms Act 1977 Yes ☐ No ☐

PART B – Property damage and business interruption (optional)

17 Can you confirm that

(i) the premises are in a good state of repair and the buildings do not have listed status and were built after 1800 Yes ☐ No ☐

(ii) the buildings are constructed of brick, stone or other non-combustible materials and roofed with slates, tiles, metal, concrete, asphalt, asbestos or other non-combustible materials Yes ☐ No ☐

(iii) the buildings are not fitted with composite insulated panels systems (internally Yes ☐ No ☐

or externally)

(iv) where the buildings have flat roof sections, the flat roof has been adequately maintained or is less than 10 years old. Yes ☐ No☐

(v) you have no property located in a basement Yes ☐ No☐

(vi) the buildings are securely locked and protected as per Appendix 3 Yes ☐ No☐

18 Do your activities include

(i) unattended heat processes or unattended overnight processes Yes ☐ No☐

(ii) the use of volatile chemicals/combustible materials not stored in accordance with The Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) Yes ☐ No☐

(iii) work with combustible metals or filling of aerosols Yes ☐ No☐

(iv) storage of branded pharmaceuticals, computer hardware, electronic components, nonferrous metals, controlled drugs or radioactive materials Yes ☐ No☐

(v) work with property very sensitive to changes in its environment or contamination, including but not limited to temperature or humidity Yes ☐ No☐

(vi) use of clean rooms Yes ☐ No☐

(vii) the creation of physical property through research and development Yes ☐ No☐

18 Can you confirm that

(i) property stored on racking does not exceed 3 meters Yes ☐ No☐ N/A☐

(ii) attended processes using heat are covered by an appropriate automatic fire suppression system; or, the operator is provided with and trained to use suitable fire suppression apparatus for the process being undertaken Yes ☐ No☐ N/A☐

(iii) where rider operated lift trucks (e.g. fork lift truck) are in operation

a. battery charging is undertaken in a dedicated and well-ventilated area, free of combustible materials. Yes ☐ No☐ N/A☐

b. vulnerable walls, supports and racking are protected from impact Yes ☐ No☐ N/A☐

(iv) extraction ducting of volatile or heat processes is compliant with EN1366-1,5,8 & 9 Yes ☐ No☐ N/A☐

19 Can you confirm that

(i) in the event of a loss suitable alternative premises and property (including stock, raw materials, research property, specialist tools/machinery and clean rooms) are available to you for the continuation of your business activities within 30 days. Yes ☐ No☐

(ii) you have no property that requires continuous power to prevent it being damaged Yes ☐ No☐

(iii) business critical information is backed up daily and removed from site at least once a week Yes ☐ No☐

PART C – Declarations (mandatory)

20 (i) Has any director, manager, partner or trustee of yours or any person insured or proposing for insurance Yes ☐ No☐

a. been convicted, or charged but not yet tried, of any criminal offence other than a motoring offence?
b. been declared bankrupt, gone into insolvent liquidation or been the subject of receivership or an administration order? Yes ☐ No ☐

(ii) Have you ever had an application for this type of insurance declined by an insurer, had a renewal of such insurance declined or had similar insurance cancelled or made subject to special conditions? Yes ☐ No ☐

(iii) Within the last five years have you or any person insured or proposing for insurance to which this proposal relates
a. had any claim, prosecution, proceedings or investigations made or instigated against them whether successful or otherwise? Yes ☐ No ☐

b. suffered any loss or made any claim (whether insured or not) which would have fallen within the scope of the proposed insurance irrespective of whether or not such loss or claim relates to the property insured or proposed for insurance? Yes ☐ No ☐

(iv) Are you or any person insured or proposing for insurance aware, AFTER ENQUIRY, of any CIRCUMSTANCE OR INCIDENT which they have reason to suppose might afford grounds for any future claim that would fall within the scope of the proposed insurance which has not already been advised to us? Yes ☐ No ☐

Important information concerning your personal information

Please carefully read the following before you sign and date the declaration.

Your insurance cover includes cover for individuals who are either insureds or beneficiaries under the policy (individual insureds). We collect and use relevant information about individual insureds to provide you with your insurance cover and to meet our legal obligations.

This information includes individual insureds' details such as their name and address [and may include more sensitive details such as information about their health and criminal convictions].

We will process individual insureds' details, as well as any other personal information you provide to us in respect of your insurance cover, in accordance with our full Markel privacy notice, a copy of which is available online at http://www.markelinternational.com/foot/privacy-policy/ or on request.

Information notices
To enable us to use individual insureds' details in accordance with current data protection laws, we need you to provide those individuals with certain information about how we will use their details in connection with your insurance cover.

You agree to provide to each individual insured this short form information notice on or before the date that the individual becomes an individual insured under your insurance cover or, if earlier, the date that you first provide information about the individual to us.

Minimisation and notification
We are committed to using only the personal information we need to provide you with your insurance cover. To help us achieve this, you should only provide to us information about individual insureds that we ask for from time to time.

You must promptly notify us if an individual insured contacts you about how we use their personal details in relation to your insurance cover so that we can deal with their queries.

Important information concerning your duty to make a fair presentation of risk

Please carefully read the following before you sign and date the declaration.

Before the insurance policy takes effect you have a duty to make a fair presentation of the risks to be insured.

A *fair presentation of the risk* is one

- which discloses to us every material circumstance which you know of or ought to know of, or

- gives us sufficient information to put us on notice that we will need to make further enquiries for the purpose of revealing those material circumstances, and
- which makes that disclosure in a manner which is reasonably clear and accessible to us, and
- in which every material representation as to a matter of fact is substantially correct and every material representation as to a matter of expectation or belief is made in good faith.

A *material circumstance* is one that would influence our decision as to whether or not to agree to insure you and, if so, the terms of that insurance. If you are in any doubt as to whether a circumstance is material you should disclose it to us.

Failure to make a fair presentation of risk could prejudice, reduce or modify your rights under the policy.

21. I declare that
    - I am authorised to complete this proposal on behalf of the Proposer
    - every statement and particular within this proposal form
        - which is a statement of fact, is substantially correct, and
        - which is a matter of expectation or belief, is made in good faith

    If any such facts, expectations and/or beliefs materially change before the insurance policy takes effect I will undertake to provide details of all such changes to you in order to comply with my obligation to provide a fair presentation of the risk to be insured under the insurance policy.

Signed : Name:

Capacity: Date:

Appendix 1

As per Part A – General information; Question 5. Please indicate which categories or ingredients are applicable; including any derivative, extract, adulterated botanical or botanical derivative or that contains or has the same or similar chemical formula, structure of function of the following substances

- 1,4 butanediol (BD) ☐
- 1,3-dimethylbutylamine, (1,3 DMBA) AMP citrate (4-amino -2-methylpentane citrate) ☐
- alosetron ☐
- anabolic steroids (natural or synthetic) ☐
- aprotinin ☐
- aristolochic acids ☐
- bismacine ☐
- botulinium toxin ☐
- cannabidiol (CBD) ☐
- cisapride ☐
- clopidogrel ☐
- cox-2-inhibitor products ☐
- dabigatran ☐
- dextropropoxyphene and/or propoxyphene ☐
- diethylstilbestrol (DES) or stilbestrol ☐
- dimethylamylamine (DMAA) ☐
- ephedra or ephedrine or ephedrine derivatives ☐
- fenfluramine or dexfenfluramine ☐
- finasteride ☐
- flupirtine ☐
- gamma buyrolactone (GBL) ☐
- gamma hydroxy butyrate (GHB) ☐
- germander ☐
- germanium ☐
- glyburide ☐
- hydroquinone ☐
- isotretinoin ☐
- jin bu huan ☐
- kava-kava (piper methysticum) ☐
- larrea tridentata (chaparral) ☐
- lobelia ☐
- l-tryptophan (only when used for or as part of a physically ingestible product) ☐
- magnolia ☐
- meprobamate ☐
- methyl methaerylate (MMA) ☐
- methylphenidate ☐
- metoclopramide ☐
- mibefradil ☐
- mitragyna speciosa (kratom) ☐
- olmesartan ☐
- orlistat ☐
- phentermine ☐
- phenylpropanolamine ☐
- p-Phenylenediamine (PPD) ☐
- primodos ☐
- pyrrolizidine alkaloids (comfrey) ☐
- stephania tetrandra ☐
- tetrazepam ☐
- thalidomide ☐
- thiazolidindiones ☐
- thimerosal ☐
- triclosan (where sold in the United States of America) ☐
- Triphenyl Phosphate (TPP/TPHP) ☐
- trovafloxacin ☐
- varenicline ☐
- yohimbe ☐

Appendix 2

As per Part A – General information; Question 6. Please indicate which product categories are applicable;

- anticonvulsants ☐
- antidepressants ☐
- antiepileptics ☐
- antiperspirants containing aluminium ☐
- attention deficit hyperactivity disorder (adhd) drugs ☐
- atypical antipsychotics ☐
- birth control or fertility products (other than male and female condoms) ☐
- bisphosphonates ☐
- blood products / products derived from human blood ☐
- di-(2-ethylhexyl)phtalate (DEHP) ☐
- diazepines oxazepines or thiazepines ☐
- dopamine agonists ☐
- gadolinium-containing contrast agents ☐
- gliptins ☐
- hmg coa reductase inhibitor products
- (statins) ☐
- hormone pregnancy tests (HPT) ☐
- hormone replacement products / hormone replacement therapy products (HRT) ☐
- hydroxyethyl starch (HES) solutions for infusion ☐
- hydroxyquinoline derivative products ☐
- impotence; medicinal products for treatment of ☐
- incretin mimetics ☐
- infusion systems and pumps ☐
- metal-on-metal implants ☐
- opiates/opioids ☐
- pregnant women; medicinal products specifically designed for ☐
- prohibited or restricted herbal ingredient (as defined by MHRA or local equivalent) ☐
- retinoids ☐
- silicone gel or liquid silicone when used as part of an implantable medical device ☐
- supplements used in body building or sport other than Sports Nutrition ☐
- surgical mesh used in urogynecology ☐
- Traditional Chinese Medicine or herbal medicines not granted a traditional herbal registration ☐
- vaccines (prophylactic) ☐
- weight management; medicinal products specifically designed for ☐

Appendix 3

SECURELY LOCKED AND PROTECTED SHALL MEAN

(a) automatic intruder detection systems are operational throughout unoccupied areas of your premises and out of business hours, which

(1) Were installed by a NSI Gold certified installer

(2) incorporate both perimeter and infrared detection, and

(3) are connected to an automatic intruder alarm, and

(4) features confirmed technology, and

(5) signals to a manned central station via a dual path communication system

(b) level 1 police response is in force at all premises

(c) all external doors (and any internal doors leading to any part of the Buildings not in your sole occupation) are secured with either

(1) if an aluminium door: a cylinder mortice deadlock, or

(2) if an armoured plate door: the door manufacturer's locks as supplied, or

(3) if a UPVC door: a multi-point locking system incorporating a minimum of 3 deadbolts

(4) if any other type of single leaf door

(i) where the door thickness is at least 4.5 cm: a five lever mortice deadlock to at least British Standard 3621 together with a 17.5 cm boxed steel striking plate

(ii) where the door is less than 4.5 cm thick: a deadlocking rim latch keyed into the deadlock position or a mortice deadlock and two key operated security bolts engaging with the door frame and with internal operation only

(5) if double leaf doors:

(i) the standing leaf is secured with internal surface mounted key operated security bolts or concealed flush bolts sited top and bottom engaging with the door frame and the floor, and

(ii) the final closing leaf is secured with either a lock fitted as above dependent on door type or both leaves fitted with a coach-bolted locking bar secured with a close shackle padlock (or, if the locking bar is sited internally, either a close or open shackle padlock) having at least five levers

(6) if a designated fire door: either

(i) a panic bar locking system incorporating bolts which engage both the head and sill of the door frame, or

(ii) a mortice lock having specific application for emergency exit doors and which is operated from the inside by means of a conventional handle and/or thumb turn mechanism

(d) all external ground floor windows, accessible windows and/or skylights, originally designed to open are secured with either

(1) key operated window locks, or

(2) adequately secured metal bars or grilles, external or internal metal shutters or internal collapsible metal security grill, or

(3) screwed shut.