

# Specialty Lines

## UNDERWRITERS

1233 North Mayfair Road, Suite 208 • Milwaukee, WI 53226  
Phone: 414-778-3560 • Fax: 414-778-3598

### APPLICANT'S INSTRUCTIONS:

1. Answer all questions completely. Please attach extra sheets as required. Incomplete or illegible applications may be discarded.
2. Application must be signed and dated by the owner, partner, or officer not earlier than 45 days before the proposed effective date of coverage.
3. Please read the statements at the end of this application carefully. Thank you!

## NUTRACEUTICAL/DIETARY SUPPLEMENT ADDENDUM TO THE LIFE SCIENCES APPLICATION

1. Does the applicant have any past, present or planned association with any of the following:  

<input type="checkbox"/> Animal derived products	<input type="checkbox"/> DES (diethylstilbestrol and/or dienestrol)
<input type="checkbox"/> Oral contraceptives	<input type="checkbox"/> Ephedrine alkaloids including ephedra
<input type="checkbox"/> Hormone Replacement Therapy	<input type="checkbox"/> Ephedrine
<input type="checkbox"/> Vaccines	<input type="checkbox"/> Ma Huang
<input type="checkbox"/> Weight reduction products	<input type="checkbox"/> Bishops tea
<input type="checkbox"/> Psychotropic products	<input type="checkbox"/> Chi Powder
<input type="checkbox"/> SSRI products	<input type="checkbox"/> Methylephedrine
<input type="checkbox"/> Products that are known teratogens	<input type="checkbox"/> Norephedrine
<input type="checkbox"/> Products that are known mutagens or any of the following substances and/or their derivatives?	<input type="checkbox"/> Pseudoephedrine
<input type="checkbox"/> Androstenedione and any derivatives and all steroid precursors	<input type="checkbox"/> Norpseudoephedrine
<input type="checkbox"/> Aristocholic Acid (Aristolochia)	<input type="checkbox"/> Fenfluramine or Dexfenfluramine
<input type="checkbox"/> Bitter Orange	<input type="checkbox"/> Gamma Hydroxy Butrate (GHB)
<input type="checkbox"/> Botanicals: (Any and all adulterated botanicals)	<input type="checkbox"/> Gamma Butyrate (GBL)
<input type="checkbox"/> Akebia spp.	<input type="checkbox"/> Butanediol (BD)
<input type="checkbox"/> Aristolochia spp.	<input type="checkbox"/> Germanium (Teucrium chamaedrys)
<input type="checkbox"/> Asarum spp.	<input type="checkbox"/> Germanium
<input type="checkbox"/> Bragantia spp.	<input type="checkbox"/> Jin bu huan
<input type="checkbox"/> Clematis spp.	<input type="checkbox"/> Kava (Piper methysticum)
<input type="checkbox"/> Cocculus spp.	<input type="checkbox"/> L-Tryptophan
<input type="checkbox"/> Diploclisia spp.	<input type="checkbox"/> Lobelia (Lobelia inflata)
<input type="checkbox"/> Fang Chi	<input type="checkbox"/> Organ/glandular extracts
<input type="checkbox"/> Guang fang ji	<input type="checkbox"/> Oxycodone
<input type="checkbox"/> Kan-Mokutsu	<input type="checkbox"/> Pennyroyal oil (hedeoma pulegloides)
<input type="checkbox"/> Menispermum spp.	<input type="checkbox"/> Phentermine
<input type="checkbox"/> Mokutsu	<input type="checkbox"/> PPA (Phenylpropanolamine)
<input type="checkbox"/> Mu Tong, Fang ji	<input type="checkbox"/> Pyrrolizidine alkaloids
<input type="checkbox"/> Sinomenium spp.	<input type="checkbox"/> Skullcap or skullcap (scufellaria lateriflora)
<input type="checkbox"/> Chapparral (Larrea divaricata)	<input type="checkbox"/> Stephania and Magnolia
<input type="checkbox"/> Colloidal Silver	<input type="checkbox"/> Swine Flu vaccine
<input type="checkbox"/> Comfrey (symphyum officinale)	<input type="checkbox"/> THG (tetrahydrogestinone)
	<input type="checkbox"/> Willow Bark
	<input type="checkbox"/> Yohimbe (Pausinystalia yohimbe)

If "Yes", please explain:

---

---

2. Do any of your products carry the USP Certification Mark (United States Pharmacopeia)? Yes  No   
If "Yes", which ones? \_\_\_\_\_
3. What percentage of your dietary supplements carry a USP or NF (National Formulary) seal on the label? \_\_\_\_\_
4. Do any of your products advertise any health claims? Yes  No   
If "Yes", which ones? \_\_\_\_\_  
How have they been substantiated? \_\_\_\_\_
5. Has any reputable peer-reviewed journal published any study that you have conducted? Yes  No
6. Have any of your products fit the definition of a "new dietary ingredient" per FDA regulations? Yes  No   
If "Yes", have the required pre-market safety reviews been conducted per FDA regulations? Yes  No
7. Have any of your products ever had an active ingredient that would be defined as a "drug" by the FDA? Yes  No   
If so, what are they? \_\_\_\_\_
8. Do any of your products contain animal derived ingredients? Yes  No   
If "Yes", please explain: \_\_\_\_\_
9. Do all your products clearly state that the FDA has not evaluated them? Yes  No
10. Do you promote any of your products for use in children? Yes  No
11. Are all of your products for human consumption only and clearly marked as such? Yes  No
12. From which countries do you obtain raw ingredients from? \_\_\_\_\_
13. Does your labeling clearly state all necessary warnings concerning safety information and any known side effects including contra-indications? Yes  No
14. Do you have a formal disclosure policy in place for making safety concerns known? Yes  No   
Please provide a copy of that policy.
15. Has the FDA or FTC ever cited you for any regulatory violations? Yes  No
16. Do you have a safety surveillance team? Yes  No   
Please describe.
17. What recommendations has that team made in the past three years?  
\_\_\_\_\_  
\_\_\_\_\_
18. How many adverse events have been reported to you and/or the FDA concerning your products in the last three years? \_\_\_\_\_
19. How many customer complaints have your received concerning your products in the last three years? Do you have a formal procedure for the analysis and handling of these complaints? \_\_\_\_\_
20. How often do you conduct quality control/assurance audits of manufacturing, regulatory, and sales marketing operations? \_\_\_\_\_ Are there any outstanding safety issues from these audits? Yes  No