

## **Questionnaire for Nutraceuticals & Dietary Supplements**

*(This questionnaire is to be used as a supplement to our standard products application)*

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1. Are any of your products designed to promote weight gain, weight loss, muscle enhancement or increased metabolism?  Yes  No

2. Do any of your products make health claims? If yes, which ones? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Have any of these claims been substantiated?  Yes  No

3. Do you promote any of your products for use in children?  Yes  No

Do you provide any products for use in pre-natal or post-natal care?  Yes  No

4. Are any of your products used for female breast augmentation?  Yes  No

Are any of your products used for sexual enhancement and/or male enhancement?  Yes  No

5. Do your labels indicate all appropriate warnings concerning safety information, and known side effects including contraindications known by you?  Yes  No

6. Do you have a formalized disclosure policy in place on making safety concerns known?  Yes  No

7. Do you have any past, present, or planned association with the any of the following:

- |                          |                               |                          |                       |
|--------------------------|-------------------------------|--------------------------|-----------------------|
| <input type="checkbox"/> | Animal derived products       | <input type="checkbox"/> | Stephania or Magnolia |
| <input type="checkbox"/> | Steroids or anabolic hormones | <input type="checkbox"/> | Chaparral             |
| <input type="checkbox"/> | Ephedrine                     | <input type="checkbox"/> | Gamma Hydroxybutyric  |
| <input type="checkbox"/> | Ma Haung                      |                          | Acid (GHB)            |
| <input type="checkbox"/> | Synephrine                    | <input type="checkbox"/> | Chomper               |
| <input type="checkbox"/> | Androsteredione               | <input type="checkbox"/> | Germander             |
| <input type="checkbox"/> | Aristolochic Acid             | <input type="checkbox"/> | Comfrey               |
| <input type="checkbox"/> | St. John's Wort               | <input type="checkbox"/> | Germanium             |
| <input type="checkbox"/> | Butanediol                    | <input type="checkbox"/> | Tiractricol           |
| <input type="checkbox"/> | Gamma Butyrolactone (GBL)     | <input type="checkbox"/> | Creatine              |
| <input type="checkbox"/> | Dehydroepiandrosterone (DHEA) | <input type="checkbox"/> | Jin Bu Huan           |
| <input type="checkbox"/> | Xi Xin                        | <input type="checkbox"/> | Willow Bark           |
| <input type="checkbox"/> | Wormwood                      | <input type="checkbox"/> | Lobelia               |
| <input type="checkbox"/> | Kava                          | <input type="checkbox"/> | Yohimbe               |
| <input type="checkbox"/> | Senna                         | <input type="checkbox"/> | L-tryptophan          |
| <input type="checkbox"/> | Melatonin                     | <input type="checkbox"/> | Chromium Picolinate   |
| <input type="checkbox"/> | Menadione                     | <input type="checkbox"/> | Vanadium              |

8. If you answered yes for question 7 please identify which products have been used, currently are being used, or are planned for future use. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

What percentage of your total sales are derived from those products? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

9. Do any of your dietary supplements carry a USP (United States Pharmacopeia) or NF (National Formulary) seal on the label?  Yes  No

If yes, what percentage? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

10. Has the FDA or FTC cited you for regulatory violations in the last 5 years?  Yes  No

11. Have any of your products ever had an active ingredient that would be defined as a drug by the FDA?  
 Yes  No

If yes, what are they? \_\_\_\_\_  
\_\_\_\_\_

12. Do all your products indicate the FDA has not evaluated them?  Yes  No

13. Do any of your products have similar names that might reflect they are intended for same use as an approved drug?  
 Yes  No

14. Do you comply with GMP's?  Yes  No

15. How many adverse events have been reported to you and/or FDA concerning your products in the last 3 years?

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

Have any adverse events resulted in remedial actions? (If yes, provide details)? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

16. How many customer complaints have your received concerning your products in the last 3 years concerning safety?

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

Do you have SOP's concerning the analysis and handling of these complaints? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

17. What is your experience and/or qualifications for manufacturing this type of product? \_\_\_\_\_

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

\*Signature of Applicant

Date

Title (Owner, Partner, Officer)

\* Signing this application does not bind the applicant or the company to complete the insurance.