

## Nutraceutical and Dietary Product Supplemental Application

*(This supplement is to be used in addition to our standard products application)*

Applicant Name: \_\_\_\_\_

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

b. List all product names and total projected sales for these products, and attach all product labels for each product listed below. (Attach separate sheet if necessary to list additional products)

Name	Projected Annual Sales	Labels Attached
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes

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

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

c. List all product names and total projected sales for these products, and attach all product labels for each product listed below. (Attach separate sheet if necessary to list additional products)

Name	Projected Annual Sales	Labels Attached
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes

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

- |  |  |
|--|--|
| <input type="checkbox"/> Androsteredione<br><input type="checkbox"/> Aristolochic Acid<br><input type="checkbox"/> Bitter Orange (Citrus Aurantium)<br><input type="checkbox"/> Butanediol<br><input type="checkbox"/> Chaparral<br><input type="checkbox"/> Chomper<br><input type="checkbox"/> Colloidal Silver<br><input type="checkbox"/> Comfrey<br><input type="checkbox"/> Dehydroepiandrosterone (DHEA)<br><input type="checkbox"/> Ephedra, Pseudoephedrine, Ma Haung<br><input type="checkbox"/> Gamma Butyrolactone (GBL)<br><input type="checkbox"/> Gamma Hydroxybutyric Acid (GHB)<br><input type="checkbox"/> Germander,<br><input type="checkbox"/> Germanium<br><input type="checkbox"/> Jin Bu Huan<br><input type="checkbox"/> Kava<br><input type="checkbox"/> Lobelia<br><input type="checkbox"/> Pennyroyal Oil<br><input type="checkbox"/> Stephania or Magnolia<br><input type="checkbox"/> Steroids or hormones<br><input type="checkbox"/> Synephrine<br><input type="checkbox"/> Tiratricol<br><input type="checkbox"/> Yohimbe<br><input type="checkbox"/> Any derivatives of any of the above ingredients. Is so please list. _____<br>_____<br>_____ | <input type="checkbox"/> Animal derived products<br><input type="checkbox"/> Black Cohosh<br><input type="checkbox"/> Chromium Picolinate<br><input type="checkbox"/> Creatine<br><input type="checkbox"/> Melatonin<br><input type="checkbox"/> Menadione<br><input type="checkbox"/> Senna<br><input type="checkbox"/> Scullcap<br><input type="checkbox"/> Wormwood<br><input type="checkbox"/> Willow Bark<br><input type="checkbox"/> Vanadium<br><input type="checkbox"/> Any derivatives of any of the above ingredients. Is so please list<br>_____<br>_____<br>_____<br>_____ |
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b. Please list all of your products that include any of these ingredients checked off, attach all product labels for each product listed below and your total projected sales for each of these products. (Attach separate sheet if necessary to list additional products)

<u>Name</u>	<u>Projected Annual Sales</u>	<u>Labels Attached</u>
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes

4.a. Do you promote any of your herbal products for use in children?  Yes  No

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

c. List all product names and total projected sales for these products and attach all product labels for each product listed below? (Attach separate sheet if necessary to list additional products)

<u>Name</u>	<u>Projected Annual Sales</u>	<u>Labels Attached</u>
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes
_____	_____	<input type="checkbox"/> Yes

5.a. Do any of your products make health claims? If yes, please identify the products.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

b. Have any of these claims been substantiated?  Yes  No

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

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

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

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

10.a. Have any of your products ever had an active ingredient that would be defined as a drug by the FDA?

b. If yes, what are they?

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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

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

13. Do you comply with Good Manufacturing Practices (GMP)?  Yes  No

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

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

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16. Have you ever recalled products because of a potential product safety hazard?  Yes  No  
(If yes, provide details including percent of recovery):

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17. Do you plan the introduction of any new products?  Yes  No  
If yes, please explain:

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18. Have you discontinued or plan to discontinue any products?  Yes  No  
If yes, please explain and include the date(s) discontinued:

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19. How many customer complaints have you received concerning your products in the last 3 years concerning safety (If any please describe)?

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

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