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## NutraPLUS Application

**Notice:** If the policy for which application is made is for claims made coverage: coverage applies only to "claims" first made during the "policy period," unless an extended reporting period is exercised.

Please read the policy carefully.

If space is insufficient to answer any question fully, attach a separate sheet. If response is none, state NONE.

### I. APPLICANT INFORMATION

- A. Full Name of Applicant: \_\_\_\_\_
- B. Organization / Company Name: \_\_\_\_\_
- C. Principal business address: \_\_\_\_\_
- D. List of names of all predecessor organizations of the applicant: \_\_\_\_\_  
 \_\_\_\_\_
- D. Audit Contact Name & Phone: \_\_\_\_\_
- E. Website Address: \_\_\_\_\_
- F. Years in business: \_\_\_\_\_ G. Proposed Effective Dates: \_\_\_\_\_ to \_\_\_\_\_
- H. Applicant is a:  corporation  partnership  sole proprietorship  limited liability company (LLC)  
 Other: Specify: \_\_\_\_\_
- I. Is any principal, member, shareholder, officer or director of the Applicant associated with any other person, entity or organization that is involved in the manufacture, distribution or sale of dietary supplements? ..... Yes  No
1. If Yes, please explain: \_\_\_\_\_
- J. Is the Applicant controlled by, owned by, or commonly owned, affiliated or associated with any other organization? ..... Yes  No
1. If Yes, provide details: \_\_\_\_\_

### II. DIETARY SUPPLEMENT DETAILS

- A. Total estimated annual gross sales for products listed in Part II., Question B.:
- |                             |                |         |
|-----------------------------|----------------|---------|
|                             | Domestic (USA) | Foreign |
| 1. Upcoming Year (Estimate) | _____          | _____   |
| 2. Prior Year (Actual)      | _____          | _____   |
- B. Provide the following information for those products the Applicant wants coverage for. If products below are identified by category, please attach a listing of all products within such category for which you seek coverage.  
 NOTE: Only those products listed below will be considered for coverage.

Products and Goods	Applicant acts as:					# of Yrs.	% of Gross Receipts	Products & Goods Sold to:				
	M	W	R	I	MR			W	R	C	O	

M: manufacturer W: wholesaler R: retailer I: importer MR: manufacturer's rep. C: consumer direct O: Other (describe)

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1. Are any of the above listed products marketed for children or for use in pre-natal or post-natal care? .....Yes [ ] No [ ]

2. If Yes, identify such products: \_\_\_\_\_

C. Provide the name(s) and description(s) of all product(s) sold by the Applicant that is/are not dietary supplement(s) as defined under the Dietary Supplement Health and Education Act of 1994 (and amendments thereto) or by the FDA:

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

NOTE: Any product containing an ingredient listed on endorsement: MEIL 1317 Exclusion - Designated Ingredients will not be covered unless a specific exception stating such ingredient as an exception to the exclusion is included in the policy offered by the Company. This endorsement is attached for review and acknowledgment by the Applicant.

D. Percentage of total estimated gross sales to be generated from the following type products:

Weight Loss \_\_\_\_\_%      Body Building & Sports Nutrition \_\_\_\_\_%      Sexual Enhancement & Erectile Dysfunction \_\_\_\_\_%

If any %, provide details, including product description, form and usage: \_\_\_\_\_

E. Provide details on products the Applicant is seeking coverage for that contain the following ingredients or other ingredients designated on the MEIL 1317:

Designated Ingredient	Name of the Product Containing the Ingredient	Ingredient Dosage	Estimated % of Sales
Creatine Yes[ ] No[ ]			
Kava Yes[ ] No[ ]			
Magnolia Yes[ ] No[ ]			
Yohimbe Yes[ ] No[ ]			
Identify Other: _____			

NOTE: Attach similar details for any other product containing any ingredient stated on the MEIL 1317. ALSO provide legible copies of labels for any product containing any of the designated ingredients with this application.

F. Provide a description of all mergers, acquisitions, and divestitures involving the Applicant within the past five (5) years: \_\_\_\_\_

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

1. Is Applicant considering any merger, acquisition or divestiture within the next twelve (12) months? . Yes [ ] No [ ]

G. Provide a description of any recent or planned changes in mix of Applicant's products, including discontinuing any product: \_\_\_\_\_

H. Does the Applicant contract the manufacturing of any of its product(s) to others?.....Yes [ ] No [ ]

1. If Yes, please provide the manufacturer's name and address, and attach a copy of the contract to this application: \_\_\_\_\_

2. If Yes to II.H., to the best of the Applicant's knowledge has any company listed in question II.H.1. recalled or is it considering recalling a product that the Applicant was involved with? ..... Yes [ ] No [ ]

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3. If Yes to II.H.2., please provide details: \_\_\_\_\_  
\_\_\_\_\_

I. Does the Applicant perform contract manufacturing of products devised, designed, or formulated by others? ..... Yes [ ] No [ ]

1. If Yes, please provide the names, addresses, and products of all entities for whom Applicant performs contract manufacturing: \_\_\_\_\_

2. If Yes to II.I., to the best of the Applicant's knowledge has any company listed in question II.I.1. recalled or is considering recalling a product that the Applicant was involved with? ..... Yes [ ] No [ ]

3. If Yes to II.I.2., please provide details: \_\_\_\_\_  
\_\_\_\_\_

J. If the Applicant is a wholesaler or retailer of domestically sourced products, please list the manufacturers: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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**III. PROCESSING AND QUALITY CONTROL**

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A. Is the Applicant a member of the Natural Products Association (NPA) or NSF International?..... Yes [ ] No [ ]

B. Is the Applicant compliant with FDA Current Good Manufacturing Practices? ..... Yes [ ] No [ ]

C. Has the Applicant ever been found to be out of compliance with FDA Good Manufacturing Practices?..... Yes [ ] No [ ]

D. In the past five years, has the FDA issued a Warning Letter or a Form FDA 483 to the Applicant?... Yes [ ] No [ ]

1. If Yes, attach a copy of each notification and all relevant documents.

E. Has the Applicant or will the Applicant use ingredients imported from foreign suppliers?..... Yes [ ] No [ ]

1. If Yes, please list the ingredients and describe the Applicant's Quality Assurance Program and countries of origin:  
\_\_\_\_\_  
\_\_\_\_\_

F. Does the Applicant have a quality control and testing procedure? ..... Yes [ ] No [ ]

1. If Yes, how long are quality control and testing records kept? \_\_\_\_\_

G. Can the Applicant identify its own product(s) from those of competitors by product packaging, design, labeling and formulation? ..... Yes [ ] No [ ]

H. Do records indicate to whom the Applicant's product was sold and the date of sale? ..... Yes [ ] No [ ]

I. Does the Applicant have a full time employee in charge of quality control and testing? ..... Yes [ ] No [ ]

J. Does the Applicant conduct pre-production testing of raw materials?..... Yes [ ] No [ ]

K. Do the Applicant's records show a specific identification number for each package sold?..... Yes [ ] No [ ]

L. Does the Applicant have a program to withdraw known or suspected defective products from the market? ..... Yes [ ] No [ ]

M. Has the Applicant or any other entity ever recalled or is the Applicant or any such entity(ies) considering recalling Applicant's product or an ingredient or component thereof? ..... Yes [ ] No [ ]

1. If Yes, please provide details: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

N. Is the Applicant aware of or have knowledge of any fact, incident, circumstance, situation, condition, defect or suspected defect which may lead to a recall?..... Yes [ ] No [ ]

1. If Yes, please provide details: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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O. Have any of the Applicant's products or ingredients or components thereof, ever been the subject of any investigation, enforcement action, or notice of violation of any kind by any governmental, quasi-governmental, administrative, regulatory or oversight body?..... Yes [ ] No [ ]

1. If Yes, please provide details: \_\_\_\_\_

P. Are imported products, materials and ingredients tested for contamination and verification that they conform to what was ordered?..... Yes [ ] No [ ]

Q. Are the Applicant's formulas and designs reviewed, tested or verified by outside labs? ..... Yes [ ] No [ ]

**IV. LABELS**

A. Are the Applicant's labels fully compliant with all applicable FDA and FTC Regulations? ..... Yes [ ] No [ ]

B. Does the Applicant use outside legal counsel to review and approve labeling?..... Yes [ ] No [ ]

C. Have the Applicant's labels ever been found to be non-compliant with FDA or FTC Regulations? ..... Yes [ ] No [ ]

1. If Yes, please provide details: \_\_\_\_\_

D. Do any of the Applicant's labels make health claims for specific diseases or health-related conditions? ..... Yes [ ] No [ ]

E. Do all the Applicant's labels include a disclaimer that the FDA has not evaluated the claims on its labels and that its products are not intended to diagnose, treat, cure or prevent any disease? ..... Yes [ ] No [ ]

F. Do all the Applicant's labels include specific dosage directions and warnings? ..... Yes [ ] No [ ]

**V. ADVERTISING**

A. Is the Applicant's advertising fully compliant with all applicable FDA and FTC Regulations? ..... Yes [ ] No [ ]

B. Does the Applicant use outside legal counsel to review the Applicant's advertising and confirm it is in compliance with FDA and FTC Regulations? ..... Yes [ ] No [ ]

C. Has the FDA or FTC ever contacted the Applicant about the Applicant's advertising? ..... Yes [ ] No [ ]

1. If Yes, please provide details: \_\_\_\_\_

**VI. LOSS HISTORY**

A. Has any claim for Product or General Liability been made against any person(s) or organization(s) proposed for this insurance during the last five (5) years?..... Yes [ ] No [ ]

1. If Yes, provide five (5) year hard copy, currently valued, carrier produced loss runs for all claims, including those against any predecessor.

2. Attach a detailed description for any loss exceeding \$10,000.

B. Is (are) any person(s) or organization(s) proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a Product or General Liability claim such as would fall under the proposed insurance? ..... Yes [ ] No [ ]

1. If Yes, provide details: \_\_\_\_\_

**VII. INSURANCE INFORMATION**

A. Requested Coverage\*:

1. Limits of Liability Requested: \$ \_\_\_\_\_ / \$ \_\_\_\_\_

2. Deductible Requested: \$ \_\_\_\_\_

\*The Company does not guarantee to offer a quote nor does it guarantee requested limits or attachment.

B. Current Coverage:

1. Current Carrier: \_\_\_\_\_ 2. Limits of Liability: \_\_\_\_\_

3. Deductible or SIR: \_\_\_\_\_ 4. Premium: \_\_\_\_\_

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5. Expiration Date: \_\_\_\_\_ 6. Retroactive / Prior Acts Date(s): \_\_\_\_\_

7. Is the current carrier offering renewal?.....Yes [ ] No [ ]

C. Has any insurer declined, canceled, or nonrenewed any Product Liability Insurance or any similar insurance on behalf of any person(s) or organization(s) proposed for this insurance? ..... Yes [ ] No [ ]

1. If Yes, provide details. \_\_\_\_\_

**NOTICE TO THE APPLICANT - PLEASE READ CAREFULLY**

No fact, incident, circumstance, situation, condition, defect or suspected defect indicating the probability of a claim or action for which coverage may be afforded by the proposed insurance is now known by any person(s) or organization(s) proposed for this insurance other than that which is disclosed in this application. It is agreed by all concerned that if there is knowledge of any such fact, incident, circumstance, situation, condition, defect or suspected defect any claim subsequently emanating therefrom shall be excluded from coverage under the proposed insurance.

This application, information submitted with this application and all previous applications related hereto and material changes to any of the foregoing of which the underwriting manager, Company and/or affiliates thereof receives notice is on file with the underwriting manager, Company and/or affiliates thereof and is considered physically attached to and part of the policy if issued. The underwriting manager, Company and/or affiliates thereof will have relied upon this application and all such attachments in issuing the policy.

For the purpose of this application, the undersigned authorized agent of the person(s) and organization(s) proposed for this insurance declares that to the best of his/her knowledge and belief, after reasonable inquiry, the statements in this application and in any attachments, are true and complete. The underwriting manager, Company and/or affiliates thereof are authorized to make any inquiry in connection with this application. Signing this application does not bind the Company to provide or the Applicant to purchase the insurance.

If the information in this application and any attachment materially changes between the date this application is signed and the effective date of the policy, the Applicant will promptly notify the underwriting manager, Company and/or affiliates thereof, who may modify or withdraw any outstanding quotation or agreement to bind coverage.

If the policy for which application is made is for claims made coverage, the undersigned declares that the person(s) and organization(s) proposed for this insurance understand that coverage for which this application is made applies:

- (i) Only to "claims" first made during the "policy period"; unless an extended reporting period is exercised. If an extended reporting period is exercised, the policy shall also apply to "claims" first made during the extended reporting period; and
- (ii) Unless amended by endorsement, the limits of liability contained in the policy shall be reduced, and may be completely exhausted by "claim expenses" and, in such event, the Company will not be liable for "claim expenses" or the amount of any judgment or settlement to the extent that such costs exceed the limits of liability in the policy and unless amended by endorsement, "claim expenses" shall be applied against the "deductible".

**WARRANTY**

I/We warrant to the Company, that I/We understand and accept the notice stated above and that the information contained herein is true and that it shall be the basis of the policy and deemed incorporated therein, should the Company evidence its acceptance of this application by issuance of a policy. I/We authorize the release of claim information from any prior insurer to the underwriting manager, Company and/or affiliates thereof. The Applicant has a continuing duty to supplement, correct and update the information in this Application up to the time a binder is issued.

Note: This application is signed by undersigned authorized agent of the Applicant(s) on behalf of the Applicant(s) and its owners, principals, partners, directors, officers and employees.

Must be signed by the owner, principal, partner, executive officer or equivalent within 60 days of the proposed effective date.

\_\_\_\_\_  
Name of Applicant

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date

**Notice to Applicants:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and subjects the person to criminal and civil penalties.

**THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.**

**EXCLUSION - DESIGNATED INGREDIENTS**

This insurance does not apply to claims arising from the importation, manufacture, distribution, sale, use or ingestion of the following, whether as the primary ingredient or in combination with other ingredients or as a synthetic or cloned version, and whether marketed under the name(s) listed below or any other name:

1. Germander.
2. Lobelia.
3. Yohimbe.
4. Jin Bu haun.
5. Gamma Hydroxy Butrate (GHB); Gamma Butyrate (GBL); 1,4 Butanediol (BD).
6. Ephedra sinica, Ephedra. E. equisetina, Mahuang, Ephedra Alkaloid, Pseudoephedrine, Ephedrine or any other Ephedra derivatives or extracts.
7. Aristolochia spp., Aristolochia, Aristolochic acids, Aristolochia fangchi, Aristolochia spp., Asarum spp., Bragantia spp., Clematis spp., Akebia spp., Cocculus spp., Diploclisia spp., Menispermum spp., Sinomenium spp., Mu Tong, Fang ji, Guang fang ji, Fang Chi, Kan-Mokutsu, Mokutsu and any adulterated botanicals, botanical derivatives or other products that contain aristolochic acid, aristolochic acid derivatives or aristolochic acid extracts.
8. Stephania, Stephania spp, or any adulterated botanicals, botanical derivatives or any other products that contain Stephania, or any Stephania derivatives or extracts.
9. Magnolia, or any adulterated botanicals, botanical derivatives or any other products that contain Magnolia, or any Magnolia derivatives or extracts.
10. Kava, ava, ava pepper, awa, kava root, kava-kava, kawa, Piper methysticum Forst. f., Piper Methysticum G. Forst, rauschpfeffer, intoxicating pepper, kava kava, kava pepper, kawa kawa, kawa-kawa, kew, Piper methysticum, sakau, tonga, wurzelstock, yangona.
11. Glyburide, unlabeled glyburide, Liqiang 4, Liqiang Xiao Ke Ling (Liqiang Thirst Quenching Efficacious).
12. Bismacine, also known as Chromacine.
13. DMAA; dimethylamylamine; AMP Citrate; DMBA; and 4-amino-2-methylpentane citrate.
14. Kratom, Mitragyna speciosa, mitragynine extract, biak-biak, cratom, gratom, ithang, kakuam, katawn, kedemba, ketum, krathom, krton, mambog, madat, Maeng da leaf, nauclea, Nauclea speciosa, thang, either in natural or synthetic form or any of their derivatives, alkaloids or extracts.
15. Cannabidiol (CBD), cannabinoids, and any derivative, extract or constituent of cannabis, natural or synthetic.
16. Natural anabolic steroids; synthetic anabolic steroids.

Accepted By: \_\_\_\_\_ Date: \_\_\_\_\_

Must be signed by the owner, principal, partner, executive officer or equivalent within 60 days of the proposed effective date.

Endorsement MEIL 1317 01 16