THE *IMCJ* SUPPLEMENT QUALITY AUDIT FORM

TO: _____

RE: Program of Vendor Quality Certification and "The *IMCJ* Supplement Quality Audit Form"

The companies that supply us with dietary supplements (our vendors) are the essence of our success. Our business cannot exist without quality materials and services. Therefore, to ensure the quality of the products we provide our patients (capsules, tablets, tinctures, powders, etc), we have embarked on a Program of Vendor Quality Certification designed to foster working partnerships with all of our valued vendors of dietary supplements. We feel that developing an open, trusting, cooperative relationship with each company is a prerequisite to selling any of your products.

Vendor certification is an important component of a Total Quality Management System. It (1) assures that a vendor's product is produced, packaged, and shipped under controlled processes that result in consistent conformance to our requirements and (2) supports the concept of "quality at the source" by placing responsibility for such quality on you, the vendor.

As a medical practice, we feel very strongly about the importance and need for certification and have included it as a major cornerstone of our business philosophy. Thus, we seek to identify and do business with natural product suppliers and/or manufacturers that meet or exceed the following objectives.

OBJECTIVES:

We are seeking vendors who

1. are interested in making certification a standard part of doing business;
2. are committed to partnering with us;
3. develop internal programs to assure consistent quality, good communication, timely delivery, and best overall cost;
4. have in place or are willing to put in place a documented quality system. This would include
   a) adhering to all the applicable US Food and Drug Administration (FDA) regulatory requirements as put forth in its guidelines for current Good Manufacturing Practices (cGMPs) for the manufacture of nutritional supplements;
   b) having or being willing to create a comprehensive quality control testing program that assures raw material and finished products are fit for use—eg, they are authentic, meet label claims for strength and stability through the expiration dating period, and have maximum freedom from contamination; and
   c) having the ability to provide legitimate proof that your products meet set quality standards.

To this end, please answer questions on "The *IMCJ* Supplement-Quality Audit Form" below and return your completed audit to us.

In an effort to protect your intellectual property and confidentiality, you may provide only the first and last sheets for audit reports, standard operating procedures, and other multipage forms as proof of proper documentation.

We request that you return this form **within 1 month** of the fax date.

We greatly appreciate your time and effort.

Clinician/Practice Name: _____
Address: _____
_____
E-mail: _____
Phone:_____ Fax: _____

The *IMCJ* Supplement Quality Audit Form
VENDOR INFORMATION
Corporate Name:
Address(es), telephone/fax numbers, and web address(es) (Please give contact information for all work sites if more than one.):
Name, address, telephone/fax numbers, and web address(es) of parent organization, if applicable:
List all the brand names you own (» Please attach additional pages if necessary.):
Your company's contact personnel (Provide name, phone extension, email address.): Plant Manager: _____ QA/QC Manager: _____ Head Purchasing Agent:_____

CGMP & QUALITY PROCEDURES Check 1 column or circle 1 answer for each.			
	*Y	N	N/A
1. Does your company have a Quality Control Unit?			
2. Does the quality unit have the authority to approve/reject the following:			
a. Procedures	a	a	a
b. Specifications	b	b	b
c. Test methods and results	c	c	c
d. Instrument/control calibrations	d	d	d
e. Raw ingredients/components	e	e	e
f. Finished ingredients	f	f	f
g. Packaging materials	g	g	g
h. Labels	h	h	h
i. Processing records	i	i	i
j. Forms (ie, batch production records, inventory control records, performance logs, etc)	j	j	j
k. Reprocessing operations	k	k	k
3. Which current Good Manufacturing Practices (cGMPs) do you follow? a. Food cGMPs b. FDA cGMPs for Dietary Supplements c. We have no cGMP system	 a b c		
4. Is there a plant-wide internal cGMP audit program? a. If yes, how often do you audit? (Please circle answer.) Yearly Every 2 yrs Every 5 yrs Other: _____ » If yes, please attach a copy of your internal audit form.	___	___	___
5. Have you ever been independently audited or certified for cGMP compliance?	___	___	___
If audited, by whom?			
a. NPA. Date of Last Audit: _____	a	a	a
b. NSF. Date of Last Audit: _____	b	b	b
c. USP. Date of Last Audit: _____	c	c	c
d. TGA. Date of Last Audit: _____	d	d	d
e. FDA. Date of Last Audit: _____	e	e	e
f. Other: _____ Date of Last Audit: _____	f	f	f
» If yes, please attach audit report as proof that you successfully passed the cGMP audit.			
6. Please provide a copies of the following: » The table of contents for your written standard operating procedures (SOPs) » The table of contents for your SOP forms			
7. Is there a pest control program in use at the facility? a. Do written records exist for pest control inspections? » If yes, please attach an example. b. How often do pest control inspections occur? _____	___ a	___ a	
8. Does a written GMP training program exist for new and veteran employees? » If yes, please attach an example.	___	___	
9. Are customer concerns or complaints reviewed by the quality unit? a. If no, whom are they reviewed by? _____	___	___	

*Y = yes, N = no, N/A = not applicable

RAW MATERIAL QUALITY

Check 1 column or circle 1 answer for each.

	*Y	N	N/A
10. Do you accept a certificate of analysis in lieu of independent testing of raw materials? » If yes, please provide a written, detailed rationale for how you control the quality of your raw materials at the time of receipt.			
11. Do you have an in-house QC lab? •If yes, please list the name, phone extension, fax, and email of supervisor: _____ _____ •If yes, how many analysts by level of education are in the lab? GED _____ BS _____ MS _____ PhD _____	___	___	___
12. If you use a contract QC lab(s), is it audited by any of the following a. Company personnel b. A third party c. Not audited •If audited, how often? (Please circle answer).) Yearly Every 2 yrs Every 5 yrs Other: _____ » If not audited, please provide a written, detailed rationale for how you control the quality of your raw materials.	a b c		
13A. When doing in-house or independent testing of BOTANICAL raw materials are they tested for the following? (» Please provide 2 examples of test data for each item "a" to "g.")			
a. Identity (to authenticate material or botanical genus and species) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	a	a	
b. Potency (if a potency claim exists) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	b	b	
c. Heavy Metals (lead, mercury, cadmium, arsenic) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	c	c	
d. Microbiology Profile (bacteria, yeast, and mold) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	d	d	
e. Herbicides and Pesticides Residue • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	e	e	

*Y = yes, N = no, N/A = not applicable

RAW MATERIAL QUALITY (Continued) Check 1 column or circle 1 answer for each.			
	***Y**	**N**	**N/A**
13A. (continued) When doing in-house or independent testing of BOTANICAL raw materials are they tested for the following? (Please provide 2 examples of test data for each item "a" to "g.") f. Aflatoxins • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ g. Chemical Solvent Residue • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ » **Note**: If your company either does not test 1 or more of the items listed in "a" to "g" and/or does not test *every* batch of received material for these parameters, please provide a detailed rationale proving how omitting such testing is not missing a quality parameter.	f g	f g	
13B. When doing in-house or independent testing of NON-BOTANICAL raw materials are they tested for the following? (Please provide 2 examples of test data for each item "a" to "e.") a. Identity (to authenticate material or botanical genus and species) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ b. Potency (if a potency claim exists) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ c. Heavy Metals (lead, mercury, cadmium, arsenic) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ d. Microbiology Profile (bacteria, yeast, and mold) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ e. Chemical Solvent Residue • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____ » **Note**: If your company either does not test 1 or more of the items listed in "a" to "g" and/or does not test *every* batch of received material for these parameters, please provide a detailed rationale proving how omitting such testing is not missing a quality parameter.	a b c d e	a b c d e	

*Y = yes, N = no, N/A = not applicable

BOTH RAW MATERIAL & FINISHED PRODUCT QUALITY Check 1 column or circle 1 answer for each.			
	***Y**	**N**	**N/A**
14. Are retained samples maintained for "a" and "b"? If yes, for how long are they retained? a. Raw materials? _____ b. Finished goods? _____	 a b	 a b	
15. Metal Detection: a. Do you run all in-process (raw) materials through a metal detector (for any metals dropped in the product)? • If so, by what method? _____ b. Are finished products metal detected? • If so, by what method? _____ c. Please explain how the effectiveness of metal detection measures is evaluated (attach additional pages if necessary). _____	 a b 	 a b 	

FINISHED PRODUCT QUALITY Check 1 column or circle 1 answer for each.			
	***Y**	**N**	**N/A**
16. Do you put expiration/"use by" dates on your products? » If no, please provide a rationale for how you prove you meet label claim.	___	___	
17. Are your finished products tested for label-claim potency prior to release for sale? » If yes, please provide full test data for 3 different products. » If no, please provide a rationale for how you prove you meet label claim.	___	___	
18. Do you perform label-claim potency testing (stability testing) to verify that the product meets label claim throughout the expiration dating/use by period? » If yes, please provide stability potency assays on 3 different finished product batches that were tested to verify the expiration date claim. » If no, please provide a detailed rationale for how you prove that you have met the label claim through the dated period.	___	___	
19. Are any major food allergens (eg, milk, eggs, fish, shellfish, nuts, wheat, peanuts, and soybeans) produced, handled, or stored at or near this facility? » If yes, please describe what precautions are taken to avoid cross-contamination. » If yes, please describe what cautionary language is placed on product or material labels to warn of the potential presence of allergens.	___	___	
20. Is the production for any finished goods subcontracted? » If yes, please explain how you ascertain quality control (eg, identity, strength, no adulteration or contamination) for the other facility/facilities?	___	___	

*Y = yes, N = no, N/A = not applicable

"Associate yourself with men of good quality if you esteem your own reputation."
— George Washington