Appendix D

Supplier Evaluation Questionnaire					
Company Name:					
Company Information:	☐ Corporate ☐ Public ☐ Private ☐ Partnership				
Phone / Fax:		Website:			
Company Address:					
City:		State / Zip Code:		Country:	
Years in business:		Facility Size (Square foot):			
Supplier Type:	☐ Raw Material ☐ Packaging Component ☐ Other Materials				

Supplier Contact Information:

Management:		Title:	
Phone:		Email:	
Quality:		Title:	
Phone:		Email:	

Supplier Evaluation Questionnaire

Questionnaire: Please provide thorough and detailed responses to all applicable sections. Enter an N/A or line through a section if the section is not applicable to supplier services.

Question	Comments
Regulatory History:	
Has the facility been inspected by the FDA?	
If so, indicate dates for the last two inspections and submit copies of FDA Establishment Inspection Reports, Form 483's and/or Warning Letters received.	
Has the facility been inspected by the Department of Health or any other regulatory body?	
If so, what was the compliance rating? Submit copies of the report issued.	
What type of facility registration do you have with the FDA, DEA, or USDA? Provide registration numbers.	
What standard(s) do you employ for your manufacturing operations? (Food GMPs - 21 CFR 117; ISO, GFSI, other)	
Does the facility have any certifications? If so, list the Certifications and renewal dates.	
Has the facility been inspected by a third-party?	
If so, indicate the name of the third party, date for the last inspection and submit copies of the report issued.	

Supplier Evaluation Questionnaire

Question	Comments
Personnel:	
Who is responsible for the Quality System at the facility? Provide their name, title, and document (biography, resume, or CV) that summarizes their education, experience, and training.	
Who is responsible for material manufacturing at the facility? Provide their name, title, and document (biography, resume, or CV) that summarizes their education, experience, and training.	
Submit organizational chart(s) showing departments/sections, titles of key personnel, and reporting structure.	
What is the total number of personnel working at the facility?	
Are Job Descriptions available to indicate the qualification requirements and job functions for all personnel?	
Describe the on-the-job training program employed and submit the corresponding SOP that governs the process. Submit copies of two associates training records along with the training matrix.	
What are the requirements for personnel hygienic practices at the facility?	
Facility:	
What are the normal hours of operation of the facility?	
What is the square footage of the facility, including all buildings?	

Supplier Evaluation Questionnaire

Question	Comments
Facility:	
List all of the operations performed at the facility (farming, harvesting, manufacturing, packaging, labeling, testing, holding, and/or distribution).	
Are multiple facilities used to conduct any of the farming, harvesting,manufacturing, packaging, labeling, testing, holding, or distribution operations?	
Does the facility contract out any operations? If so, indicate what type of operations are performed by third parties, and by whom.	
List the major equipment available at the facility.	
Is all equipment qualified prior to use?	
Is all equipment calibrated prior to use and on a routine basis consistent with the manufacturers recommendations?	
What type of preventative maintenance program is in place?	
Are refrigerated and freezer storage available at the facility? How are these controlled temperature units verified to be suitable for use?	

Supplier Evaluation Questionnaire

Question	Comments
Facility:	
Is the facility continually monitored for temperature and humidity?	
Has the facility where materials are held been mapped for temperature and humidity?	
Explain the Environmental Monitoring program used at the facility to limit material, product, and contact surface contamination. Attach a copy of the SOP that details this program.	
Summarize the pest control program employed at the facility. Provide a copy of the associated pest control SOP.	
Are written procedures for cleaning of equipment and production areas developed?	
If so, are records for cleaning maintained? Submit copies of cleaning logs.	
How is cleaning of equipment and production rooms verified?	
Does the facility have a dedicated Sanitation Supervisor?	
Is line clearance performed on production rooms/equipment prior to production?	

Supplier Evaluation Questionnaire

Question	Comments
Facility:	
Is there positive air pressure in the production rooms?	
What are the protective clothing requirements in the GMP areas? (ex: hairnets, lab coats, shoe covers etc.)	
Quality Systems:	
Provide a document(s) that gives an overview of the quality system such as an SOP Index or Quality Manual.	
Explain the document control system that is utilized at the facility.	
Is an electronic document control system in use? If so, indicate the software type.	
Are electronic software packages validated to be suitable for use?	
Submit a copy of your change control procedure to indicate how revisions to controlled processes and documents are managed at the site.	
How are customers notified of changes to processes, records, specifications, test methods, or contract terms that may impact their product?	

Supplier Evaluation Questionnaire

Question	Comments
Quality Systems:	
Summarize the quality incident system and provide a copy of the SOP on Material Reviews.	
Are there procedures in place for managing and investigation Out of Specification (OOS), Out of Trend (OOT), and aberrant or unusual test results?	
Briefly explain the process of conducting an OOS investigation. Submit a copy of the Out of Specification (OOS) procedure.	
Is a specific format used to document an OOS investigation? Submit a copy of the form used.	
What is the procedure for handling deviations to test methods, manufacturing records, or controlled processes?	
Is there an established process for salvaging and re-distributing returned materials?	
Summarize the procedure used to handle complaints. Does the SOP include a description of what defines and Adverse Event (AE)?	
Is there a separate procedure on the classification and reporting of Serious Adverse Events (SAEs)?	

Supplier Evaluation Questionnaire

Question	Comments
Quality Systems:	
How is a customer notified of an AEs and SAEs complaint received by the supplier in regards to their material?	
Is a procedure available for corrective and preventative action plans? Summarize the procedure.	
Food Safety, HACCP and Food Defense	
Is there a HACCP program in place?	
If so, list all the CCPs and CPs for the program.	
Were the CCPs and CPs equipment validated? If Yes, what qualifications were performed? (IQ, OQ, PQ)	
What is the revision frequency of the HACCP program? Is the HACCP program revised when changes to ingredients, equipment or procedures are made?	
Are control limits established using scientific data and or/regulatory guidelines? provide control limits for all CCPs and CPs.	
Are non-conformities at critical control point documented and corrective actions reviewed?	
Is there a written Foreign Supplier Verification Program (FSVP) in place? Submit copies of the FSVP procedures.	

Supplier Evaluation Questionnaire

Question	Comments
Food Safety, HACCP and Food Defense	
Is there a written Hazard Analysis and preventive controls program in place? (PCHF or Food Safety plan)	
If so, submit copies of the Food Safety Plan/ PCHF and examples of monitoring records for each control.If you answered "NO", when and how do you intend to be in compliance with above requirements?	
List all the hazards that require preventive control?	
Do you have a written Supply Chain program? If so, submit copies.	
Is there a written supplier qualification and management program in place? Submit copies of the SOP/Program.	
Are there written procedures for storage and approval of cleaning chemicals? If so, submit SOP.	
Is there a Food Defense program in place? If so, Provide a copy.	
Is there limited access control for employees and visitors to the facility and the production rooms?	
Is there CCTV video monitoring present at the facility?	

Supplier Evaluation Questionnaire

Question	Comments
Materials	
Are all incoming materials and components received into a Quarantine status? Provide a copy of the SOP that governs this process.	
Who is responsible for the release of incoming materials and components from Quarantine and what are the criteria used to make this decision?	
Is there a physically segregated Quarantine area? If so, what personnel have access to this area?	
What status indications such as Quarantine, Released, Hold, and Reject are utilized at the facility? Define each.	
Is an electronic system used to control the status of materials and products? If, so has this system been validated to comply with 21 CFR 11, *Electronic Records, Electronic Signatures*?	
Are all materials clearly identified with a description, item number, lot number, quantity, and expiration date at all times?	
Are all materials and products identified with the assigned status indications at all times?	
Are all materials and products determined to be OOS, assigned a Reject status?	

Supplier Evaluation Questionnaire

Question	Comments
Materials	
Is there a physically segregated Reject area? If so, what personnel have access to this area?	
How is the destruction of rejected material performed and documented?	
Are all Returned Dietary Supplement clearly identified?	
Is there an Allergen program in place at the facility? If so, please describe.	
How are material labels controlled at the facility?	
Is a physically segregated Label Room utilized to control access to labels? If so, what personnel are authorized in this room?	
What are the label reconciliation requirements at the facility? Attach a copy of the SOP that dictates these.	
Are the packaging components free of BPA?	

Supplier Evaluation Questionnaire

Question	Comments
Master Manufacturing Record (MMR)	
Has an MMR been established for every material manufactured?	
Does each MF indicate the intentional overage that is utilized for each ingredient in the product?	
Do the intentional overages applied to the MF account for manufacturing variability, test method variability, ingredient interactions, and ingredient degradation?	
Has an MMR been established for every product formulation and at each batch size?	
Is the MF included as part of the MMR?	
Does the MMR include detailed instructions for each point, step, or stage of the manufacturing process? Submit an example MMR template.	
Is there a separate manufacturing and packaging MMR?	
What is the nomenclature used for the unique batch or lot number that is assigned to every manufactured batch? Attach a copyof the SOP that dictates this system.	

Supplier Evaluation Questionnaire

Question	Comments
Master Manufacturing Record (MMR)	
Is a Batch Production Record (BPR) generated for each product lot that is manufactured?	
Is the executed BPR an exact copy of the MMR?	
Does the completed BPR reference equipment and facility (room) cleaning requirements and logs?	
What is the process of obtaining a representative and statistical product sample? Is this dictated in the MMR or SOP?	
Describe the procedure for determining whether a material may be reprocessed. Attach a copy of the Reprocessing SOP.	
Is the customer notified prior to any reprocessing of their material or product? How is this communicated?	
Where are reprocessing instructions documented?	
How are the actual steps dictated in the reprocessing instructions executed and documented?	
Who is responsible for the release of manufactured material for distribution and what are the criteria used to make this decision?	
How is the final release of a manufactured material documented?	

Supplier Evaluation Questionnaire

Question	Comments
Specifications	
Are all incoming materials sampled and inspected using a statistical and representative number of samples? What criteria are used? Attach inspection SOP.	
Where are incoming materials sampled? What are the environmental controls in the area?	
Is there an established Raw Material Specification for each incoming raw material? Submit a Raw Material Specification template.	
How is the documentation of the testing, in accordance to the Raw Material Specification documented?	
Is every lot of Raw material and finished material tested for everything as specified on the Specification?	
Is a Raw Material Qualification Program in place? If so, please provide brief explanation of program and submit SOP.	
What typical tests are used for in-process material testing?	
Are In-process Material Specifications established for all materials?	
Where are tests in accordance to In-process Material Specifications documented?	

Supplier Evaluation Questionnaire

Question	Comments
Specifications	
Is there an established Finished Material Specification for each manufactured material?	
How is the documentation of the testing, in accordance to the Finished Material Specification documented?	
Is a Finished Product Qualification Program in place? If so, please provide brief explanation of program and submit SOP.	
Does each Raw Material, In-Process, and Finished Material Specification address the identity, purity, strength, composition, and lack of potential contaminants? Is there an SOP that dictates this? If so, attach SOP.	
Laboratory Operations:	
Does the facility have an in-house laboratory that performs raw material, in-process material, and finished material testing?	
Are third party Contract Laboratories used to perform testing of raw material, in-process material, and finished material testing? If so, what is the qualification process for the laboratory? Submit the SOP that governs this process.	

Supplier Evaluation Questionnaire

Question	Comments
Stability:	
How many and what type of environmental / stability chambers are available at the facility?	
What is the current capacity of the chamber storage?	
Have all of the stability chambers been qualified and mapped for temperature and humidity?	
Are all of the temperature and humidity devices calibrated before use and at a frequency dictated by the manufacturer?	
How are stability protocols maintained, managed, and utilized?	
Who prepares stability summary reports and at what frequency?	
Distribution:	
How are distribution records documented and maintained?	
Is there traceability for all distributed product to the consumer?	
Is there a written recall procedure?	
Are Mock recalls performed by the facility? If so, how often?	
Is an electronic system used for the distribution of product? If so, identify the system employed.	

Supplier Evaluation Questionnaire

Question	Comments
Distribution:	
If an electronic system is used, has it been validated to comply with the requirements of 21 CFR 11, *Electronic Records, Electronic Signatures*?	
Are shipments received secured and sealed upon arrival? Is there inspection performed on the trailers delivering the materials. Submit copies of receiving and inspection procedures.	
Records	
How are records maintained at the facility?	
What are the storage duration requirements for records generated and used at the facility? Submit a copy of the SOP that governs records retention.	
Are customers informed prior to the destruction of any records pertaining directly to their product?	

Questionnaire Completed By:

Name:		Title:	
Phone:		Email:	
Signature:		Date:	

Questionnaire Reviews and Assesses By:

Name:		Title:	
Phone:		Email:	
Comments			