Audit Form

Section	Audit Item	Audit Evaluation
Subpart B	**Personnel**	
111.10	Procedures have been established that define work requirements for personnel to prevent microbial contamination from illness or hygienic practices.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.10	Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing, and sanitization, etc. prior to starting work and at any time whereby personnel can become soiled/contaminated.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.10	Procedures for removal of jewelry and other appropriate coverings.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.10	Procedures for use of impermeable gloves, hairnets, caps, beard covers, etc. and for restrictions on use of food, drinks, tobacco, etc. in areas whereby product contamination could occur. Procedures have been established to prevent contamination from all extraneous sources.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.10	Appropriate change rooms are available if needed and there is adequate storage of personal effects.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.12	Personnel must be qualified and have adequate training, experience and/or education necessary to perform job functions.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.12	Quality responsibilities are distinct and separate from operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.13	Procedures have been established to define the requirements for personnel who will supervise activities.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.13	Personnel who are designated as supervisors are qualified and have written requirements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.14	Procedures have been established and records are maintained documenting compliance to these procedures.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.12	Job descriptions are available for all personnel have received GMP and appropriate for their assigned functions.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart C	**Physical Plant and Grounds**	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15a	Grounds have been properly maintained through removal of litter and waste, cutting of grass and weeds adjacent to the plant, maintenance of roads and parking lots, providing adequate drainage, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15a4	Waste treatment and disposal is adequate and does not provide a source of potential contamination.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15a5	Production Facility is maintained in a clean and sanitary condition and in a proper	☐**Acceptable**

Audit Form

	state of repair.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15	Entrances to the facilities are properly controlled and maintained to prevent contamination.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15c	Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and adequate under the conditions of use.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15c3	Cleaning and sanitizing agents, pesticide, and fungicides have been identified, used and held and stored in a manner that protects against raw materials and in-process or finished products, and against contamination of processing equipment, and packaging materials.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15d1,2	Procedures have been established to prevent entrance to the facility by pets and animals, including screens and barriers, rodent traps, insect traps or lights, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15d3	Pest control procedures have been established for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15e	The water supply is safe and sanitary and under suitable temperature and pressure. Water that may contact a product contact surface or is in fact a component must meet U.S. Federal, State and Local requirements for drinking water.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15f3 **111.15e**	Water sources do not act as a potential source of contamination of the dietary supplement, either due to water purity or due to the configuration and construction of the water delivery system.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15f	Plumbing is of adequate size and design for intended usage.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15g	Sewage and waste disposal is properly plumbed from the facility and does not provide a potential source of contamination to contact surfaces, products, components, water supplies, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15f4	Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.).	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15f5	Backflow and cross-connection prevention is in place.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15h	Bathrooms are provided and are of adequate number and location.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15h	Bathrooms and wash facilities are kept clean and are not potential source of contamination to components, products, contact surfaces, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15i	Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing of personnel.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15j	Solid waste and trash are disposed of appropriately and not allowed to accumulate.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed**

Audit Form

		☐ **In Process** ☐ **N/A**
111.15j2,3	Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15j4	Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.15k	Sanitation supervisors have been assigned and are qualified.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.16	Procedures have been established for cleaning of the plant.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20a	All facilities are of adequate size, construction, and design for their intended use.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20b	There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20c	There are adequate precautions against contamination by microorganisms, chemicals, filth, or other extraneous materials.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20c1	Areas have been clearly defined or separated for receiving, inspecting and identifying, holding and withholding from use components, dietary supplements, packaging, or labels that will be used.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20c2	Areas have been provided for quarantine and release of materials to be used in the manufacture, packaging, or labeling of dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20c3	Areas have been provided to separate manufacturing, packaging, labeling, and holding of different product types (e.g. foods, cosmetics, pharmaceuticals) from dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20c4,5,6,7	Separate or defined areas exist for laboratory analysis and holding of laboratory supplies and samples, cleaning of contact surfaces, packaging and labeling, and holding of components or dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20d1i	Walls, floors, ceilings can be adequately cleaned and kept in good repair.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20d1ii	Fixtures, ducts, piping, etc. are kept clean, do not drip or leak or provide a source of condensation that could contaminate components, products, or contact surfaces.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20d1iii	Adequate ventilation and airflow is provided in all areas of the facility.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20d1iv	Temperature and humidity control equipment is of adequate design for its intended function and is functioning properly.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**

Audit Form

111.20d1v	Work areas have adequate access and space, aisles are clear, etc to allow for persons to perform their duties and protect against contamination or mixups.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20e	Adequate lighting is provided in all production areas, examination areas where equipment is cleaned and examined, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20f	For lighting that is suspended or located above areas where materials or equipment are exposed are of adequate construction or lighting type to prevent contamination (use of safe-lights, fixtures, etc.).	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20g	In areas where open vessels are used, there is adequate protection against contamination, e.g. use of protective coverings, physical location, use of skimming equipment, use of screening, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.20h	Production areas do not provide a haven for pests, pest infestation, filth, etc. (adequate screening and other measures are used.).	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.23	Records have been maintained for plant cleaning, pest control, and water quality (where required) and in accordance with Subpart P.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.23	Records have been maintained to show that the quality of water, when used as a component of the dietary supplement, meets the requirements of 111.15 (e) (2).	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart D	**Equipment and Utensils**	
111.25a,b	Procedures have been established for calibration of all instruments, controls, automated, mechanical, and electronic equipment, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.25c	Procedures have been established for the cleaning and sanitization of all utensils and equipment.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.25c	Procedures and programs have been established for maintaining equipment.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a	All equipment and utensils are corrosion resistant, made of nontoxic materials, and of suitable design, construction, and workmanship for their intended use.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a2	Equipment and utensils are of appropriate design so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a3iv	Equipment and utensils are designed and constructed to withstand the environment in which they are used and do not degrade upon exposure to components, process materials, cleaning agents, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a3v	Equipment and utensils protect components and dietary supplements from contamination from ant source.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a4	Equipment and utensils are constructed as seamless, or if seams exist, are easily cleanable and do not provide a place for accumulation of potential contaminants.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**

Audit Form

111.27v	Equipment and utensil surfaces are inspected at routine intervals for signs of wear, damage, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a5	Equipment such as freezers, refrigerators, etc. that are used to hold components or dietary supplements must be functioning properly and adequately designed.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a6	Instruments and controls that are used in all areas must be accurate and precise (calibrated where necessary), maintained, and adequate in number.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27a7	Process gases that are used and contact dietary supplements, components, and contact surfaces must be controlled as not to cause contamination (e.g. filters).	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d	All equipment, instruments, utensils, contact surfaces etc. must be maintained, cleaned and sanitized as necessary.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d1	Equipment, utensils, etc. must be disassembled as necessary to assure maintenance, cleaning, and sanitization.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d2	Low moisture processing: Equipment, utensils, and contact surfaces are dry and sanitized. If wet-cleaned, drying and sanitization is performed.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d3	Wet Processing: Contact surfaces are cleaned and sanitized before use and after any interruptions. If continuous production is performed, cleaning and sanitization is performed at designated intervals.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d4	Surfaces that do not come into direct contact with components or dietary supplements are cleaned.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d5	Disposable items (single-service) are stored in appropriate containers; handled, used, dispensed of in a manner that protects against contamination.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d6	Cleaning and sanitizing agents are adequate and safe for their intended use.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.27d7	Portable equipment and utensils are properly stored after cleaning and sanitization.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.30a	Automated, mechanical, or electronic equipment must be functioning properly and be adequately designed.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.30d	Procedures are in place showing equipment is suitable for use and controls are functioning properly to maintain use.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.35b1iii	Procedures for maintenance, cleaning, sanitization of all equipment, utensils, and contact surfaces are established and records of sanitization are maintained.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.35b2	Equipment logbooks have been maintained for each equipment and include the date of use and any documentation of cleaning, sanitization, maintenance, etc. (unless the documentation is the batch record).	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed**

Audit Form

		☐ **In Process** ☐ **N/A**
111.35b4	Records are available of calibrations, inspections, and checks of any automated, mechanical, or electronic equipment.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.35b5	Backup electronic files have been maintained of the following: current software programs, outdated software programs that may be necessary to retrieve past records, and data that was entered.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.35b5ii	Backup files are an exact and complete record and are secure from alterations, erasures, or loss and damage.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart E	**Production and Process Control System**	
111.55	Production and process control systems have been implemented for each production process and/or product.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.60	Production and process have been designed to ensure the quality of the product and the Quality Control Unit has approved the control systems.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.65	Quality Control operations have been identified and implemented.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.70	Specifications have been established for components, in-process materials, labels, packaging components, and finished product.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75	A system has been established to determine if all specifications that are established have been met.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75a	Components are sampled, tested, and confirmed (released) prior to use in production.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75a2	If a Certificate of Analysis (COA) is used to confirm the component, the supplier must be qualified and documentation must be maintained for this qualification.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75a2iiD	Supplier Qualification Procedures are established and include initial qualification, periodic examination (requalification), and procedures for disqualifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75b.c	Proper testing procedures or programs have been established to determine if in process and finished product specifications for purity, composition, strength of the dietary supplement have been met.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75e	For products that are received for packaging and labeling, visual examinations are performed and documentation is available to determine whether the product meets established specifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75f	Packaging and labeling materials are visually examined, at a minimum, and are reviewed against the supplier's invoice to determine conformance with specifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.75g	Packaging and labeling of the finished packaged and labeled dietary supplement are visually examined, at a minimum, to determine that the correct packaging and labeling has been used.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed**

Audit Form

		☐ **In Process** ☐ **N/A**
111.75h	Scientifically valid methods are used and include at least one of the following, a gross organoleptic analysis, macroscopic analysis, microscopic analysis, chemical analysis, or another scientifically valid method.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.77	Procedures and controls have been established for investigation and handling of materials that do not meet specification requirements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.80	Procedures have been established for the collection of representative samples.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.83	Procedures have been established for the collection of reserve samples for each lot of finished material.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.87	The Quality Control Unit conducts all material reviews and makes disposition decisions.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.90	Procedures have been established for the handling of unexpected events.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.90a	Reprocessing controls have been established and meet all requirements and have been approved by the Quality Control Unit.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.95	Records are maintained of specifications, supplier qualification and testing to ensure product meets purity, strength, and composition.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart F	**Production and Process Control System: Requirements for Quality Control**	
111.103	Procedures have been established for the responsibility of the Quality Control operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.105	Quality Control Personnel have established roles and responsibilities.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.110	Quality Control Laboratory Operations have been established.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.113a	Quality Control Operations and responsibilities have included the authority to reject any component or product if any specification is not met.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.113b	Quality Control Personnel may authorize a treatment, in- progress treatment, or reprocessing in an attempt to correct a deviation or unexpected event, or specification deficiency.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.113c	The Quality Control person responsible for making the material review and disposition decision has documented the review and disposition decision at the time of performance.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.120	Quality Control Operations must review and approve components, labels and packaging materials for intended use.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed**

Audit Form

		☐ **In Process** ☐ **N/A**
111.123a	Quality Control Operations and authority have been established for manufacturing records.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.123a	Quality Control Operations determine if all specifications have been met (in-process, product) and approve/release or reject has been performed on each finished batch for distribution.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.1b	Quality Control has not approved and released product in any form that does not meet the specifications unless Quality Control approved deviations has been documented.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.130	Quality Control Operations have been established for returned dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.140	Quality Control Operations are documented and meet all requirements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.140	The Quality Control Unit performs GMP Internal Audits periodically. A documented corrective action file is maintained.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart G	**Production and Process Control System: Requirements for Components, Packaging, and Labels. Also for Product that is received for Packaging and Labeling as a Dietary Supplement.**	
111.153	Receiving, sampling, testing, release procedures have been established to fulfill this Subpart.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.155	Quality Control requirements have been established for components.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.160	Quality Control requirements have been established for packaging materials and labels.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.165	Quality Control requirements have been established for products that are received for packaging and labeling as a dietary supplement and bulk finished product.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.170	Rejected components, packaging, labeling, and products are appropriately quarantined and dispositioned.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.180	Records have been established and are being maintained to meet the requirements of Subpart G.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart H	**Production and Process Control System: Requirements for the Master Manufacturing Record**	
111.205	Master Manufacturing Records have been prepared for each unique formulation and batch size of the dietary supplement.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.205b1	The Master Record identifies specifications for the control points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**

Audit Form

111.210	Master Manufacturing Records contain all of the required elements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart I	**Production and Process Control System: Requirements for the Batch Production Record**	
111.255a,b	Batch Production Records are available per Subpart P for each batch of dietary supplement that has been manufactured.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.255b	The Batch Record contains complete information relating to the production of each batch.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.255c	The Batch Record follows the master record and each step is performed appropriately.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart J	**Production and Process Control System: Requirements for Laboratory Operations**	
111.303	Procedures have been established for laboratory operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.310	Laboratory facilities used are adequate for testing of components, in-process materials, and dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.310	Laboratory controls have been established and have been approved by Quality Control.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.315	Parameters have been set for laboratory controls for sampling plans, criteria for examination and testing methods, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.320	Quality Control responsibilities for laboratory test methods and examinations used to test each specification requirement have been defined and are being followed.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.325	Quality Control Operations have maintained appropriate records as required.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.70	For all products that bear expiration date or a statement of product shelf life, the shelf life must be supported.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart K	**Production and Process Control System: Requirements for Manufacturing Operations**	
111.353	Procedures, including sanitation, operation and control have been established for manufacturing operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.355	Manufacturing processes have been designed to produce a product that consistently meets specifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.360	Manufacturing Operations are conducted using adequate sanitation principles.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed**

Audit Form

		☐ **In Process** ☐ **N/A**
111.365a-g	Precautions have been taken to prevent contamination, such as micro, filth, chemical, foreign material, etc. throughout the manufacturing process.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.365h,i	Manufacturing operations have included controls in manufacturing steps to prevent contamination, including metal detection.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.365j,k	Manufacturing operations have included the identification of all process lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number, and when necessary, the phase of manufacturing.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart L	**Production and Process Control System: Requirements for packaging and labeling operations.**	
111.403	Procedures have been established for all packaging and labeling operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.410b	Packaging and labels are controlled for issuance and are reconciled after use. Note: Reconciliation is not necessary for cut or rolled labels when 100% examination is performed by appropriate electronic or electromechanical equipment during or after completion of operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.410c	Packaging and labeling materials are examined before usage to determine that they conform to the Master Manufacturing Record.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.410d	Records are maintained to allow a complete history and control of the package and labeled dietary supplement through distribution.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415	A Master Manufacturing Record has instructions for filing, assembling, packaging, labeling, and other related operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415a	Procedures have been established for cleaning and sanitizing all filling and packaging equipment and utensils.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415d	Physical separation implemented to prevent mix-ups with other components and dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415	Filling and packaging operations are appropriately protected from contaminated sources.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415e	Procedures have been established to identify unlabeled materials that will be held for future labeling operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415f	Procedures have been established for assigning a lot or batch number for each lot of packaged and labeled dietary supplement.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415g	Procedures have been established to sample a representative number of units to assure compliance with specifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.415h	Disposal procedures have been established for disposing of labels or packaging materials that are obsolete or incorrect to ensure that they are not used.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**

Audit Form

111.420a	All repacking or relabeling operations have first been approved by the Quality Control Unit.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.420b	Representative samples of each batch of repackaged or relabeled dietary supplement have been examined to determine if they conform to specifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.420c	Quality Control Unit has dispositioned each batch of repackaged or relabeled dietary supplement prior to release for distribution.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.425	An appropriate quarantine system has been established for holding any rejected packaged and labeled dietary supplement.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.425	Storage areas have been demonstrated to meet the necessary requirements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart M	**Holding and Distributing**	
111.455	Dietary supplements, components, labeling, and packaging are held under the appropriate conditions of temperature, humidity, and light and do not lead to mix-up, contamination, or deterioration.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.460	In-process materials requiring specific holding conditions (temperature, humidity, etc.) are stored appropriately.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.470	Distribution of product must occur under conditions that will protect against contamination and deterioration.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.475b1	Procedures have been established for distribution operations.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.475b2	Product distribution records have been retained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart N	**Return of Dietary Supplements**	
111.503	Procedures have been established for the handling of returned dietary supplements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.510	Returned supplements have been appropriately quarantine until dis-positioned by the Quality Control Unit.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.515	Any returned dietary supplement must be either destroyed or disposed of unless the Quality Control Unit has determined that the material can be salvaged or reprocessed.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.520	Any salvaged material has been designated by the Quality Control Unit.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.525	Any reprocessed material has met its original specification and the Quality Control Unit has appropriately dis-positioned the material (release or reject).	☐**Acceptable** ☐ **Not Acceptable**

Audit Form

		☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.530	If the reason for the return implicates other batches, an investigation has been performed to determine if those batches comply with specifications.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.535	Procedures have been established for salvage and reprocessing operations according to Subpart P.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.535b	Documentation has been maintained for material reviews and dis-positions, all testing results, any reevaluations by the Quality Control Unit for reprocessed materials.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.535d4	All Quality Control Unit evaluations and decisions have been documented.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.535	Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of the dietary supplements associated with those records or 1 year past the shelf life date, if shelf is dating is used.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart O	**Product Complaints**	
111.553	Procedures have been established describing how product complaints will be received, investigated, and documented.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.560a	All product complaints have been reviewed by a qualified person to determine if the complaint was of a failure of the dietary supplement to meet any of its specifications or quality.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.560b	The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, has been approved by the Quality Control Unit.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.560c	The investigation for a product complaint was appropriately extended to other batches, products, processes, etc.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.570a	Records for each product complaint and investigation have been maintained. Records shall be maintained for a period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.570bii	Product complaint information has included adequate information.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
Subpart P	**Records and Record Keeping**	
111.605	Procedures have been established that described the requirements for record retention under Subpart P.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.605	Records will be maintained for 1 year after the shelf life date or 2 years beyond the date of distribution of the last batch associated with those records.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
111.605	All records are maintained as original record as true copies or as electronic records.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**

Audit Form

21CFR Part 11	**Electronic Records**	
11.10	Procedures and controls have been established for electronic closed systems used to create, modify, maintain, or transmit electronic records in order to ensure the authenticity, integrity, and confidentiality of the records [Closed Systems].	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
11.10	The procedure and controls include adequate information.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
11.30	Procedure and controls have been established for use of open electronic systems. Areas of control have been identified, as necessary, per the requirements in 11.10.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
11.50	Electronic signatures conform to requirements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
11.70	Electronic and hand-written signatures have been linked to the electronic record.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
11.100-11.200	Electronic records meet requirements.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
11.300	Password and codes have been established.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
NSF	**Compliance with The Public Health Security and Bioterrorism Preparedness and Response Act of 2002**	
	Manufacturing of dietary supplements shall submit application to USFDA for registration, receive a registration number, and provide the registration number upon request.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
	Dietary Supplement and Non Prescription Drug Consumer Protection Act	
	Procedures shall be established and followed for reporting serious adverse events to the USFDA in accordance with the dietary supplement and non-prescription drug consumer protection act.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**
	Recall Procedures	
	Procedures have been established to define the recall of a product.	☐**Acceptable** ☐ **Not Acceptable** ☐ **Not Observed** ☐ **In Process** ☐ **N/A**

QA/QC Manager:	Date: