PJRFSI
CFR 111 Checklist

1.0 Audit Requirements	
1.1 Context of the Organization	
☐	1.1.1 Have individuals responsible for quality control (QC) operations been identified? Are responsibilities relating to quality distinct and separate from operations?
1.2 Leadership	
☐	1.2.2 Does management conduct a review of the quality system to assess its suitability and effectiveness at least every two years?
☐	1.2.6 Have individuals responsible for supervising sanitation activities been assigned by the organization? Are these individuals qualified to oversee these activities based on experience or training?
☐	1.2.7 Have competent supervisory personnel responsible for overseeing transportation operations been identified within the organization and received appropriate training?
1.3 Planning	
☐	1.3.1 Has a hazard analysis been conducted for each type of dietary supplement in order to identify and evaluate known or foreseeable hazards and determine if specifications or process controls are required to address them?
☐	1.3.4 Are production processes designed to ensure the quality of the product and have these control systems been approved by Quality Control management?
☐	1.3.6 Has a crisis management plan been developed to manage significant disruptive events (such as prolonged power outages or natural disasters) that may impact the manufacturer's ability to deliver safe product?
1.4 Support	
☐	1.4.1 Has a master site plan or facility diagram/floor plan been created for the site? Does it accurately reflect the current layout of the building?

☐	1.4.6 In areas of the facility where product containers are open and exposed to the environment; are adequate measures taken to protect product against contamination? These may include protective coverings, skimming equipment or proper storage/location practices.
☐	1.4.12 Are there appropriate controls to ensure the function of electronic, automated or mechanical equipment used in manufacturing in accordance with its intended use? (Such as back-up power for critical systems.) Have these controls been approved by QC personnel?
☐	1.4.15 Are changing rooms and areas to store personal belongings provided to staff? Are these areas sufficiently removed from operations or controlled in order to avoid a risk of contamination to product or product contact surfaces?
☐	1.4.25 Have pest control procedures been established and do they include the appropriate use of any pesticides, fungicides, fumigants or rodenticides used?
☐	1.4.29 Does lighting suspended or located above exposed materials or equipment use safety-type bulbs, or is the facility otherwise constructed to adequately prevent against contamination from glass?
☐	1.4.31 Are controls in place to verify the backgrounds of new, contracted, seasonal and temporary employees before they are hired?
☐	1.4.35 Are job descriptions available for all personnel, and have these individuals received food safety, GMP and other trainings appropriate for their functions?
☐ ☐	1.4.42 Are all records relating to the receiving, testing, manufacturing or shipping of product maintained for at least one year after that production batch's shelf life, or at least two years beyond the date of distribution of the last batch associated with those records? (Good record retention practices.) 1.4.46 Are backup electronic files maintained for current software programs, outdated, software programs that are necessary to retrieve past records and data? Are these records complete and secure against alterations?
1.5 Operation	
☐	1.5.6 Are all utensil surfaces comprised of corrosion-resistant, nontoxic materials that are easily cleaned? Are they inspected at regular intervals for signs of wear or damage?

☐	1.5.7 Are logbooks maintained for each piece of equipment? Do they contain the date of use and documentation of any cleaning/sanitation or maintenance activities? Documenting this information in batch records is acceptable.
☐	1.5.9 Is documentation maintained of the controls used to ensure equipment is functioning properly and in accordance with its intended use?
☐	1.5.14 Are procedures on file for cleaning the manufacturing plant?
☐	1.5.22 Are surfaces that do not come into direct contact with components or dietary supplements cleaned at a defined and effective frequency to prevent contamination?
☐	1.5.16 Are procedures for maintenance, cleaning and sanitizing all equipment, utensils and contact surfaces established and are records of sanitation activities maintained?
☐	1.5.21 Are cleaning procedures established for cleaning and sanitizing all filling and packaging equipment and utensils?
☐	1.5.17 Are cleaning compounds and sanitizing agents used at the facility both adequate and safe for their intended use?
☐	1.5.19 Are equipment, utensils and contact surfaces used for holding low-moisture components or dietary supplements ensured to be dry and in sanitary condition before use?
☐	1.5.20 If wet cleaning is performed or for wet processing, are contact surfaces cleaned and sanitized before use and after any interruptions during which the surface might have become contaminated?
☐	1.5.25 Has a foreign supplier verification program (FSVP) been effectively implemented for all direct importers of components, bulk dosage forms or dietary supplements from foreign suppliers?
☐	1.5.28 Is there a planned deviation process established to expedite approval of raw materials, packaging materials and other component suppliers on an emergency basis?
☐	1.5.32 For all water used as a component in a dietary supplement or any contact surface used in its manufacturing, are records maintained that show the quality of water complies with applicable Federal, State and local requirements?
☐	1.5.37 Are written procedures in place for retesting materials to extend shelf life?

☐	1.5.38 Are both weighing operations and sample collection conducted in a controlled area that does not present an opportunity for contamination?
☐ ☐	1.5.39 Are master manufacturing records prepared for each unique formulation and batch size of dietary supplement? 1.5.42 Does the batch production record accurately follow the master manufacturing record with all steps being performed along with relevant production information? Are these records maintained according to good record retention practices?
☐	1.5.48 Do master manufacturing records, batch logs or other records identify the process lines and major equipment used during manufacturing to indicate their contents; including the name of the dietary supplement, the specific batch or lot number, packaging material used, and the phase of manufacturing?
☐ ☐ ☐ ☐	1.5.56 Are packaging and labels controlled for issuance and reconciled after use? (Excluding cut or rolled labels that are examined 100% by electronic or equipment.) 1.5.60 Are processes established to identify unlabeled materials that will be held for future labeling operations? 1.5.61 Have procedures been established for packaging and labeling, and for assigning a lot or batch number to each lot of packaged and labeled dietary supplements? Are these materials confirmed to match the master manufacturing record before use? 1.5.62 Have procedures been established for disposing of obsolete or incorrect labels and packaging materials?
☐ ☐ ☐	1.5.64 When a process deviation occurs that could result in the adulteration of a dietary supplement or a mislabel, are the items placed under a QC hold, and are only reworked, reprocessed or treated to correct the deviation under the approval and supervision of QC personnel? 1.5.77 Are reprocessed materials required to meet their original specifications? 1.5.65 Is the final disposition decision determined by QC personnel? Are records of material reviews and disposition decisions on file and scientifically valid?
☐	1.5.68 Are dietary supplements, their components, in-process materials, labels and packaging held under appropriate conditions of temperature, humidity and light so as not to lead to deterioration, contamination or mix-up?

☐	1.5.72 Are written procedures in place for transportation operations? Are steps being taken to prevent dietary supplements from becoming unsafe during transport?
☐	1.5.73 Are product distribution records adequately maintained and are they being retained according to good record retention practices?
☐	1.5.75 Have procedures been implemented for the handling of returned dietary supplements? Do they include appropriate quarantine procedures until a QC disposition for destruction or salvage and reprocessing has been determined?
☐	1.5.78 If the reason for a return implicates other batches, is an investigation performed to determine if those batches comply with specifications?
☐	1.5.79 Are records maintained for material reviews and product dispositions of returned products? Do these include all testing results and reevaluations by the QC unit for reprocessed materials?
☐	1.6.80 Are representative samples of each batch of repackaged or relabeled dietary supplements examined to determine if they conform to specifications?
☐	1.5.80 Are these records maintained for at least one year after the shelf life date, or two years beyond the date of distribution of the last batch from those records?
1.6 Performance Evaluation	
☐	1.6.6 Are reserve samples maintained by the site and held under appropriate conditions that will not lead to mix-up, contamination or deterioration?
☐	1.6.8 Are dietary supplement ingredients sampled, tested and released prior to use in production? Unless exempted by the FDA, do these methods include at least one test or examination to verify the identity of the dietary ingredient?
☐	1.6.15 Are scientifically valid testing methods used in these assessments, such as organoleptic, macroscopic, microscopic, or chemical analysis?
☐	1.6.18 Have parameters been set for laboratory controls such as testing methods, sampling plans, criteria for examination and reference materials?
☐	1.6.21 Are product complaints reviewed by qualified personnel in order to determine if the complaint resulted from a failure of the dietary supplement to meet any of its specifications or quality?
☐	1.6.22 Are the decisions to investigate complaints as well as the final decision as a result of the investigation, including corrective actions, approved by QC personnel?

☐	1.6.24 Are records of product complaints and investigations on file and maintained according to good record retention practices?
1.7 Improvement	
☐	1.7.3 Are procedures established for a corrective and preventative action (CAPA) program for the handling all non-conformances identified within the scope of this standard?