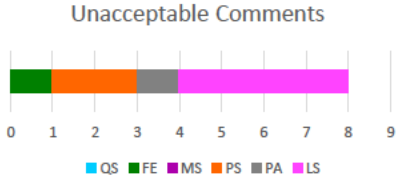
Dietary Supplements Audit Report
GMP Dietary Supplements 21 CFR Part 111 et al.

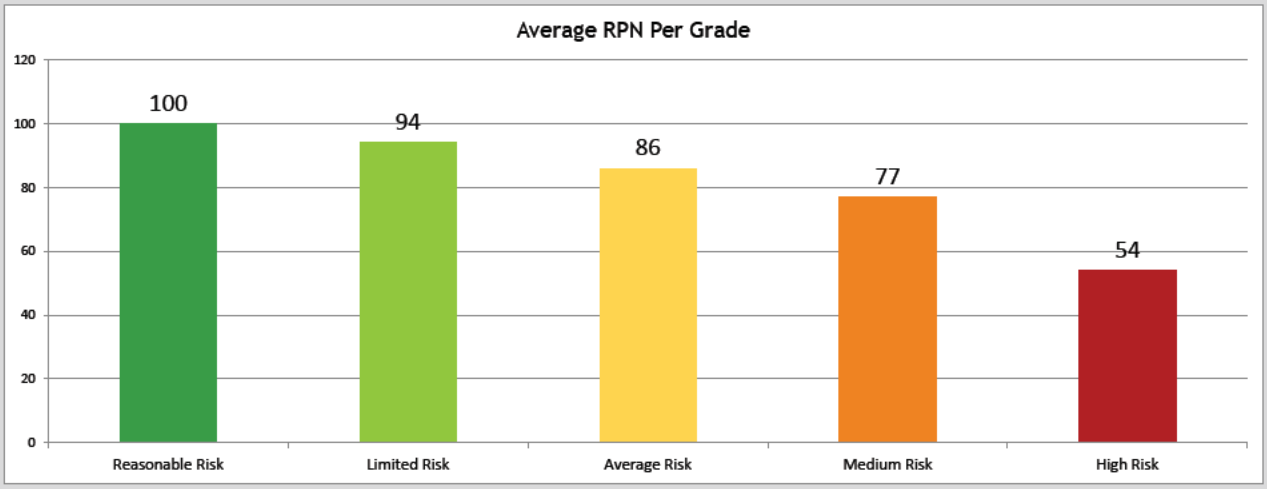
QT Report:	330998	Audit Dates:	5/21 - 5/22/2019	Report Date:	5/24/2019
Vendor Name:		*Factory Name:*		*Lead Auditor:*	
Yellow Emperor, Inc.		Yellow Emperor, Inc		Sonya Hess	
Audit Activity:		*Address:*		*Additional Auditor(s):*	
Retail Certification	Recertification Audit	510 Conger Street, Eugene, OR 97402 USA		N/A	
Risk Result:		*Nonconformances Issued:*		*Nonconformance Breakdown:*	
Risk Level	Average Risk	Critical	0		
Final Risk Priority Number	85	Major	1		
Auditor Recommendation	Follow-up Audit Recommended	Minor	7		

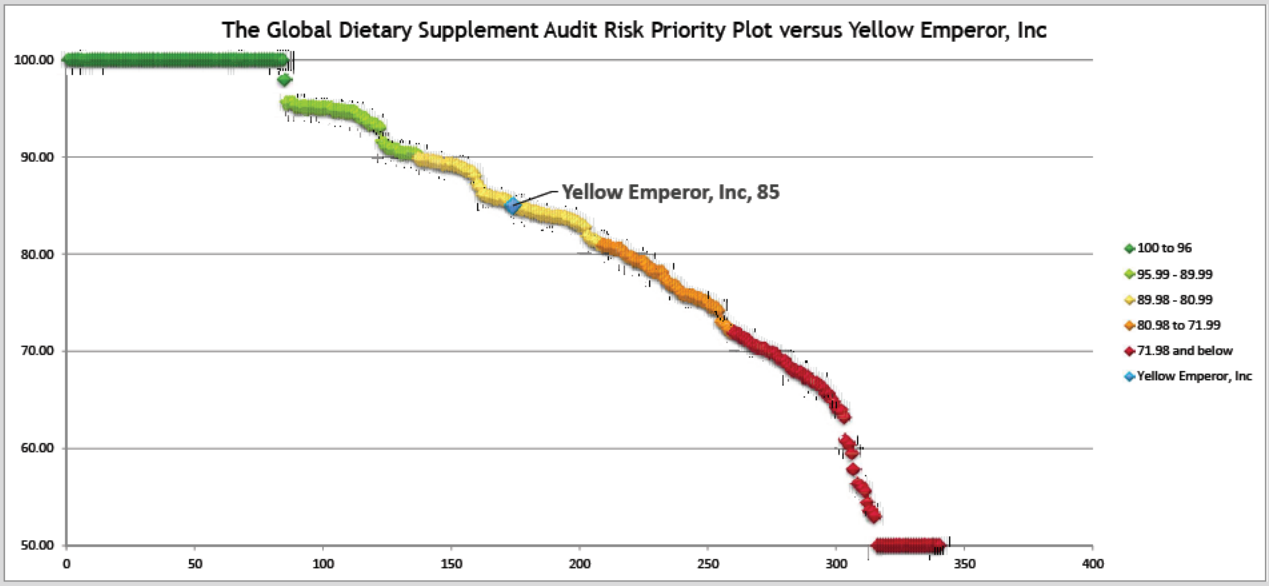
Certification/Technical Review Committee Decision:			
Decision:	*Follow-up Audit Required to Maintain Certification*	*Decision Date:*	*7/10/2019*
Follow-Up Decision:	*Grant Recertification*	*Follow-up Decision Date:*	*8/13/2019*

Certification/Technical Review Committee Notes:

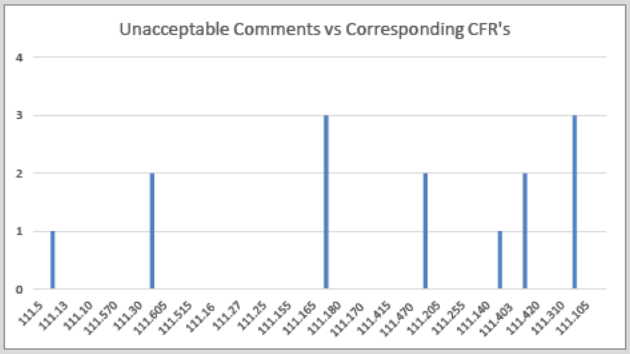
Follow Up Auditor: Sonya Hess; Follow Up Date: 8/9/2019, #349638
Based on review of follow up results, recertification can be granted.

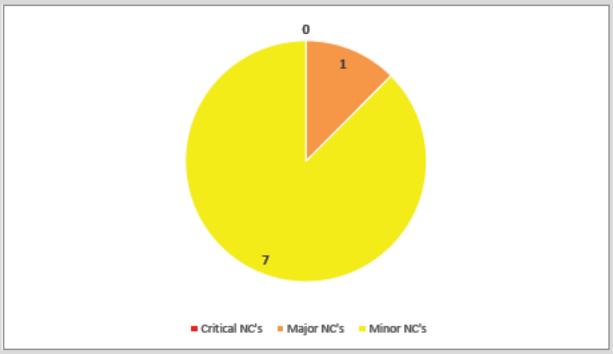
Facility Audit Information:					
Scope of audit:			*Products:*		
The Manufacturing and Packaging of Dietary Supplement Herbal Liquid Extracts			Herbal Liquid Extracts		
Types of certifications maintained:			*FDA Registration Type and Number:*		
UL, Organic, GFCO, HALAL			FDA #13601333006		
Company Representative during audit:			*Contact Information:*		
Tami King			tami@yellowemperor.com; 541-485-6664		
Additional sites under audit:					
N/A					
Production Area- Ft ^{2} :	*# Production lines:*	*Packaging Area- Ft ^{2} :*	*# Packaging lines:*	*Warehouse - Ft ^{2} :*	*Total Plant Size- Ft ^{2} :*
2,000	1	2,000	1	1,500	6,500





Specific to this Audit





	Requirement	Acceptable?	NC Type	CAR Number	Comment
	Quality System				
QS1	Confirm that the firm has registered its food facility with FDA under the Bioterrorism Act Section 305. §111.5	Acceptable			The company has registered its food facility with FDA under the Bioterrorism Act Section 305. Bioterrorism Registration Number is as follows: #13601333006.
	Training				
QS2	Confirm that the f rm has identified who is responsible for Quality Control operations, and that the responsibilities of QC staff are defined and separate from non-QC responsibilities. Establish that reviewed QC staff is competent to perform the work. 111.12(b); 111.105(a)	Acceptable			There is documentation that identifies who is responsible for quality control (QC) operations. There were documented responsibilities for the Quality Unit. The auditor reviewed the following SOPs/records: 1) QAQC-4010 - Quality Unit - 12/20/17 Quality Control Personnel were given the responsibi ity and authority to approve or reject processes specifications procedures controls tests and examinations and deviations that may affect the supplement. QC responsibilities were noted to be distinct and separate from other non-QC responsibilities for those personnel performing quality control functions. Org Chart reviewed: Yellow Emperor Organization Chart - 2/19/19 QC Staff was found to be qualified for their roles. Record: Resumes Record: Third-party certificates Record: Internal SOP training records
QS3	Evaluate the firm's procedures on personnel qualification, and ensure through a review of personnel records that personnel are in fact competent to perform the work. §111.12(a)(c)	Acceptable			There was documentation that describes the qualification requirements for personnel ensuring proper education training and/or experience to perform assigned duties. The auditor reviewed the following documentation: 1) Resumes Third-party certifications 2) Internal SOP training records Job descriptions reviewed: 1) Director of Compliance and Sanitation Supervisor 2) Research and Development and QC of Production 3) Director of Operations and Quality Control of Production 4) Production Staff
QS4	Confirm that supervisory and management personnel are qualified by education, training and experience. §111.13(a)(b)	Acceptable			A review of the firm's qualification records confirmed that *supervisory and management* personnel had the education training and experience necessary to perform their job functions. Supervisory and management qualification records reviewed: 1. Director of Comp iance and Sanitation Supervisor 2. Research and Development and QC of Production 3. Director of Operations and Quality Control of Production
QS5	Review the training program to verify that personnel are given On-the-Job and GMP training necessary to perform assigned job functions. NPA.B.1.2 Ensure the program covers scope and frequency of training, and that both new hires and veteran employees are current in training. Verify that training records include the elements required by the standard. §111.14(b)(2) & NPA.B.1.3	Acceptable			There was a written training program in place at the firm. The auditor reviewed the program for inclusion of the following elements: - job-specific training - GMP training - Defined scope and frequency of all training - New hire training - Continuing GMP education/training for veteran Employees The program contained all of these elements. The auditor reviewed the following SOPs: 1) PERS-1003 - Personnel Qualifications - 1/8/2018 Training records included date of training type of training and persons trained. The auditor reviewed the following training records: 1) New hire training - reviewed various personnel (documented on the QC Training Log) 2) Annual CGMP FSMA AER/SAER review - group training (documented on the QC Training Log)
QS6	Verify that the firm has documented policies and procedures surrounding hygienic practices to prevent contamination. Ensure such policies are being followed by personnel. 111.10(b)	Acceptable			The firm had documentation describing the personal cleanliness and hygiene measures that are taken to protect product against adulteration. The auditor reviewed the following SOPs/Policies: 1) PERS-1001 – Hygiene: Microbial - 5/15/19 2) PERS-1002 – Hygiene: General - 5/15/19 Actions to minimize contamination were evaluated against the requirements for hygienic practices per 111.10(b): • Wearing protective clothing • Personal hygiene • Use of gloves • Hand washing • Jewelry removal • Hair restraints • Storage of personal effects • Restrictions on food, drink, tobacco products • Dress code • Other precautions as applicable The auditor found that observed employees followed these measures.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
QS7	Evaluate whether personnel have been instructed to report health conditions to supervisors, and ensure the firm takes actions to exclude ill or infectious personnel from contact with product and material. 111.10(a)	Acceptable			The firm took measures to exclude employees who may be a potential source of contamination due to a health condition from those operations where contamination may occur to materials components or product. SOP: PERS-1001 – Hygiene: Microbial - 5/15/19 The following personnel were asked about the process for reporting health conditions: Employees and Supervisors 1. Production staff Employees interviewed had an understanding of these policies.
	Complaint Handling				
QS8	Review the firm's process for complaints to ensure that it includes provision for complaint assessment and investigation, and QC oversight and approval. §111.560(a)(1)(2)(b)(c); 111.553; 111.570(b)(1)	Acceptable			The firm had a documented process for dealing with complaints. SOP: CMPL-5003 - Complaints - 5/20/19 The program for complaints was assessed for the following required elements per 111.560: (1) Review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications or any other requirements of this part 111 including those specifications and other requirements that f not met may result in a risk of illness or injury; and (2) Investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications or any other requirements of this part including those specifications and other requirements that if not met may result in a risk of illness or injury. QC personnel were noted to be reviewing and approving decisions about whether or not an investigation is performed. If an investigation is performed the auditor found that it would be extended to relevant batches and records where appropriate. The company did have a procedure for the notification of the FDA in accordance with the "Dietary Supplement and Non Prescription Drug Consumer Protection Act" in the event an adverse event is communicated from a customer or consumer by way of a complaint or other means.
QS9	Check that the firm maintains complaint records as appropriate, and that records contain all required information. §111.570(a)(b)(1)(2)( )(ii)(A-F)	Acceptable			Records were kept for all complaints. Records were reviewed for their containing all of the following required items: -The name and description of the dietary supplement; -The batch lot or control number of the dietary supplement if available; -The date the complaint was received and the name address or telephone number of the complainant if available; -The nature of the complaint including if known how the product was used; -The reply to the complainant if any; and -Findings of the investigation and follow-up action taken when an investigation is performed. Records sampled by the auditor contained all of these items.
	Back-up files, Change Control, Document/Record Control				
QS10	If computer software programs are used for contro ling or assisting in the process, verify that back up files are maintained. §111.35(b)(5)(i,ii)	Acceptable			The firm maintained backup files of software and data used in the processing of dietary supplements. Such backup files were an exact and complete record of the data entered. They were secure from alteration inadvertent erasure or loss.
QS11	Analyze the firm's procedures for automated, electronic or mechanical equipment to ensure that there are proper controls in place governed by Quality personnel. 111.30(d,e)	Acceptable			Appropriate controls were established to be in place for automated mechanical and/or electronic equipment in use at the firm. Changes to the firm's operations were approved by Quality Control and were instituted only authorized personnel. Change Control SOP: CMPL-5006 - Change Control System Change control records reviewed: there are no change control records to review.
QS12	Confirm there is an established change control system in place to handle changes to GMP-related operations and GMP-related documentation. NPA.F.1.2	Acceptable			The company does have an estab ished change control system in place to handle changes to GMP-related operations and GMP-related documentation. The quality unit does approve all changes made through the change control system. Change control documents reviewed: 1: SOP approvals 2: Specification approvals 3: MMR approvals
QS13	Ensure the QC unit has control over the distribution of GMP-required documentation. NPA.F.1.3	Acceptable			The QC unit does ensure that the most recent revision of all GMP-required documentation is in use at all times.
QS14	Evaluate the firm's record retention procedures and check that records are maintained for the required amount of time, and in the format required by the FDA. §111.605(a,b,c); 111.610(a,b)	Acceptable			Records at the firm were retained for 1 year past shelf life date or 2 years beyond the date of the distribution of the last associated batch. Records kept at the firm were original records true copies or as electronic records. Records were readily available during the retention period for inspection and copying by the FDA when requested. Records reviewed: 1: UPC 814542000073 lot 10938 exp 9/17 2: UPC 816907011205 lot 10831 exp 5/17

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	Recalls/Returns/Reprocessing				
QS15	Check that there are written procedures that define the process for recalling a dietary supplement should such an event become necessary. NPA.M.1.1	Acceptable			The company had written procedures that define the process for recalling a dietary supplement should such an event become necessary. Distribution records contained the following for facilitating a recall if the need arises: - Order and ship dates - Customer name and address - Product name - Product lot numbers - Package sizes
QS16	Confirm that returned products are identified and quarantined until QC personnel conduct a material review and make a disposition decision. §111.503; 111.510; 111.530	Acceptable			There were procedures for processing returns of dietary supplements. SOP: CMPL-5002 - Returned Product - 5/20/19 Returned dietary supplements were properly quarantined and reviewed for disposition by quality control personnel. If the reason for returned supplements would implicate other batches the auditor confirmed that an investigation on each of the other batches was required to be carried out. Return records reviewed by the auditor: 1. lot 12498 2. lot 12612
QS17	Verify that returned products are destroyed or suitably disposed of, when product is not approved for salvaging or reprocessing. §111.515(a,b), 111.520	Acceptable			Returned products were destroyed or suitably disposed of unless otherwise approved for salvaging/reprocessing by QC personnel. Destruction notice/proof of disposition: Return Record for lot 12498. Returned products that the firm salvaged were found to have been appropriately approved by QC Personnel. Salvage Record: lot 12498 Salvage Record: lot 12612
QS18	If reprocessing is allowed in the firm, review the program in place for QC involvement and oversight, and that the proper records have been kept. 111.90(a)(1-2)(b)(1-2)(c); 111.260(m)(n);	Acceptable			For supplements or components that were reprocessed the auditor confirmed that Quality personnel approved such activities to ensure the quality of the finished supplement in accordance with the MMR. Quality control was found to have conducted an appropriate material review and scientifically valid disposition before the reprocessing took place. Supplements processed with reprocessed components were approved by QC personnel before release for distribution. Reprocessing was noted to be included in the batch records as appropriate. Reprocessing records reviewed: 1: lot 12498 2: lot 12612
	Facilities and Equipment				
FE1	Confirm that the firm maintains procedures for adequate maintenance of the grounds and cleaning of the facility. Verify this is being performed regularly via review of records. 111.16, 111.23(a,b)	Acceptable			There are written procedures (i.e. SOPs) that define the standard requirements for the adequate maintenance of the grounds and the cleaning of the physical plant. The auditor reviewed the following SOPs: 1) PHYS-2001 - Facilities: Exterior - 5/15/19 2) PHYS 2002 - Facilities: Interior - 5/15/19 The firm kept records for grounds maintenance and cleaning of the plant. Records of maintenance performed: 1) Internal Audit Checklists for Jan-May 2019 - weekly monthly quarterly annual 2) Daily Cleaning and Maintenance Checklists for Jan-May 2019
FE2	Confirm that there is staff assigned to supervise sanitation of the overall facility. §111.15(k)	Acceptable			There was an employee assigned to supervise overall sanitation of the facility.
FE3	Check facility grounds to ensure they are maintained in a manner that will protect against contamination, including: • Proper storage of equipment • Removing litter and waste • Cutting weeds or grass • Maintaining roads, yards and parking lots • Adequate drainage • Adequate waste treatment and disposal operations • Exercising care to prevent contamination from pests, dirt, and filth and other extraneous materials from bordering grounds. §111.15(a)(1-5)	Acceptable			The external surroundings of the facility were checked by the auditor to ensure that they were maintained in a condition to protect against contamination of components products and/or contact surfaces. The following observations were made: Litter and waste were removed in a timely manner. Grass and weeds were cut in such a way to prevent the harborage of pests. Roads yards and parking lots were maintained such that they did not pose a threat of contamination. There were adequate drainage systems in place on the plant grounds. Waste treatment and disposal systems were operated such that they were not a threat of contamination. The grounds bordering the plant were maintained in an adequate manner as to not pose a threat to contamination.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
FE4	Verify that the physical plant is maintained in a clean, sanitary condition and in good repair. §111.15(b)(1-2); 111.365(a)	Acceptable			The physical plant was maintained in a sanitary condition and was in sufficient repair.
FE5	Verify that walls, floors, pipes, fixtures, etc., are constructed of appropriate material and that they are in good repair. Confirm that there is an adequate ventilation system and environmental control program. §111.20(d)(1)(i-v)	Acceptable			The auditor further evaluated the construction of the plant to ensure there was minimal potential for contamination. Plant floors walls ceilings fixtures and work surfaces were made of easily cleanable material and were in good repair. Fixtures ducts and pipes were found to minimize the threat of contamination. Aisles or working spaces were unobstructed and of adequate width to allow for the performance of duties.
FE6	Review the size, construction and design of the firm such that it is able to facilitate maintenance, cleaning and sanitizing operations, and that space is sufficient for orderly placement of materials and equipment. §111.20(a)(b)	Acceptable			The plant was found to be suitable in size construction and design to facilitate maintenance cleaning and sanitizing operations including having adequate space for the orderly placement of equipment and materials to prevent contamination to supplements.
FE7	Evaluate the firm's design and construction for ensuring that activities are appropriately segregated, lessening the chance of mix-up or contamination. §111.20(c)(1-7)	Acceptable			The firm's layout was evaluated such that there separate and defined areas for: (1) Receiving identifying holding and withholding from use components dietary supplements packaging and labels that w ll be used in or during the manufacturing packaging labeling or holding of dietary supplements; (2) Separating as necessary components dietary supplements packaging and labels that are to be used in manufacturing from components dietary supplements packaging or labels that are awaiting material review and disposition decision reprocessing or are awaiting disposal after rejection; (3) Separating the manufacturing packaging labeling and holding of different product types including different types of dietary supplements and other foods cosmetics and pharmaceutical products; (4) Performing laboratory analyses and holding laboratory supplies and samples; (5) Cleaning and sanitizing contact surfaces; (6) Packaging and label operations; and (7) Holding components or dietary supplements. The firm was noted as having met the requirements above to prevent mix-up or contamination of component and/or product.
FE8	Review the pest control program. Effective measures should be taken to exclude pests from the plant and protect components and supplements from contamination. If insecticides, fumigants, fungicides or rodenticides are used, check that precautions are being taken to protect the product from exposure. §111.15(d)(1-3), 111.20(h), 111.23 (a)(b)	Acceptable			The auditor established that there were written procedures and supporting documentation for a Pest Control program for the faci ity and grounds. SOP: PHYS-2004 - Pest Control - 5/15/19 These procedures were noted as being sufficiently carried out to ensure the plant is protected from pests. The auditor reviewed the Pest Control service information which contained the following: Service report Contractor certification Contractor/Operator License/Credentials MSDS for all Pesticides rodenticides etc. Facility map noting locations of internal/external traps bug lights etc. Chemicals falling under the category of insecticide fumigant fungicide or rodenticide were in use at the firm. Precautions were taken to protect product from contamination.
FE9	Check that lighting is adequate where necessary for processing of dietary supplements or components, and that such lighting does not pose a threat due to breakage. §111.20(e) (f)	Acceptable			The plant has adequate lighting in the following areas. • Where components or dietary supplements are examined, processed or held • Where contact surfaces are cleaned • Where hand washing is performed • Dressing and locker rooms • Bathrooms Safety-type bulbs and/or glass was used where such breakage would result in the contamination of components or supplements in any step of preparation.
FE10	Assess bathrooms that are provided to employees for adequacy and cleanliness. §111.15(h)(1) Confirm that hand-washing stations are conveniently located to fac litate proper hygiene, and that the appropriate hand-washing implements are available to staff. §111.15(i)	Acceptable			Bathrooms in the facility were readily accessible to employees. They were noted as being clean. Hand washing facilities were provided such that they were conveniently located as needed. The auditor checked that hot running water was available and checked for the presence of soap single-use towels and/or air dryers. It was found that these items were consistently provided.
FE11	Evaluate the plumbing system for adequate installation and maintenance. §111.15(f)(1-5)	Acceptable			The plumbing system for the facility was assessed for adequate installation and maintenance such that it is able to: • Carry sufficient quantities of water to-required locations throughout the plant; • Properly convey sewage and liquid waste from the plant; • Avoid being a source of contamination of products, water supplies, or equipment; • Provide adequate floor drainage provided in all areas subject to water discharge or wet cleaning; and • Not allow backflow from, or cross contamination between, piping systems that discharge waste water or sewage and those that carry water for GMP compliant activities. The system was adequate based on the above requirements.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
FE12	Verify that sewage is disposed of into an adequate septic system, public sewage system or other adequate means. §111.15(g)	Acceptable			Sewage disposal was noted as being sufficient for use and to prevent contamination to product.
FE13	Review the trash disposal system to ensure there are an acceptable number of trash receptacles available and that they are set up to minimize contamination to supplements. §111.15(j)(1-4)	Acceptable			The auditor reviewed the trash disposal system to ensure: • minimization of odors; • mitigation of the potential to attract, harbor or become a breeding place for pests; • protection against contamination of components, dietary supplements and contact surfaces, water supplies and plant grounds; and • control of hazardous waste to prevent contamination of components, dietary supplements and contact surfaces, where applicable. The trash disposal system was found adequate per the points above.
FE14	Ensure the ventilation of the facility is adequate, and that there are controls for monitoring temperature and humidity, if relevant for the products being audited. §111.20(d)(1)(2)	Acceptable			The company had a process for assuring adequate ventilation of the facility. SOP #: PHYS 2002 - Facilities: Interior - 5/15/19 The auditor reviewed equipment used to control and monitor temperature and humidity where it is relevant for the quality of the product and found such equipment acceptable. When fans were used on the premise they were controlled such that the potential for contamination from microorganisms and particulate matter was minimal.
FE15	Water may be used in a non-component manner, including use in cleaning, hand-washing and drinking water. Ensure that water for non-component areas is safe and suitable for use. §111.15(e)(1)	Acceptable			Water in use that is not a component of the product was deemed safe and sanitary and was kept at suitable temperatures. City Testing Data 1: Eugene Water & Electric Board 2018 Water Testing Results Internal Testing Data 2: not tested Internal Testing Data 3: not tested
FE16	Analyze the firm's procedures for automated, electronic or mechanical equipment to ensure it is appropriate for its intended use and capable of operating within the required limits. 111.25(b), 111.30(a,b,c)	Acceptable			The firm maintained written provision for the calibrating inspecting and checking of automated mechanical and/or electronic equipment. SOP: EQPT-3014 – Equipment Qualification Procedures – 6/8/18 Equipment used in the processing of components and supplements were assessed such that it was: - designed or selected to ensure supplement specifications were consistently met; - capable of operating within the operating limits required by the process; - routinely cal brated inspected or checked to ensure proper performance. The auditor was to review evidence that equipment met the above criteria. Qualification documentation reviewed: Validation Log: EQ-58 High Flow CSR Quad MC2 8/17/18
FE17	Confirm that equipment and utensils are constructed such that there is no potential for contamination of components or supplements produced, including through contact with lubricants, coolants, fuel, etc. §111.27(a)(1,3,4)	Acceptable			The auditor assessed the equipment and utensils in use at the firm to ensure they were: - of appropriate design construction and workmanship for their intended use; - corrosion resistant where necessary; - made of non-toxic materials; - designed to withstand the environment in which they were used - maintained to protect dietary supplements or components from sources of contamination; - constructed such that seams were smoothly bonded and maintained to minimize accumulation of material or contaminant where applicable. The equipment/utensils reviewed were noted to have met the requirements of 111.27. They were found to be installed and maintained to facilitate proper cleaning of equipment and the surrounding area. SOP: EQPT-3000 - General Equipment Procedures - 6/8/18 Reviewed Equipment: 1) Filling/Labeling Line 2) Disti ler Mantles 3) Grinder
FE18	Ensure that equipment is designed such that components or supplements are not exposed to substances like lubricants, coolants, etc. §111.27(a)(2)	Acceptable			Equipment and utensils reviewed by the auditor were of appropriate design so as not to contaminate components or supplements with such substances as: lubricants coolants fuel metal/glass fragments filth or extraneous material contaminated water.
FE19	Assess the calibration program at the firm and whether or not proper procedures and records are kept, with the appropriate information contained therein. §111.35(b)(1)	Acceptable			There was written provision for the calibration of instruments and controls used in the manufacturing or testing of Dietary supplements. SOP: EQPT-3056 - Calibration - 5/16/19

	Requirement	Acceptable?	NC Type	CAR Number	Comment
FE20	Instruments and controls must be calibrated before use, and on a regular basis, to maintain the appropriate level of accuracy and precision. Verify the firm was performing calibrations as required, and that any instruments or controls that cannot be adjusted as need are repaired or replaced. §111.27(b)(c), 111.35(b)(3)	Acceptable			Instruments and controls were noted to have been cal brated before first use. They were also calibrated at an appropriate frequency. Calibration Record: Thermometer 8/14/18 Calibration Record: Scale SN YELL011 8/14/18 Instruments or controls that cannot be adjusted to agree with the reference standard were repaired or replaced as necessary to assure accuracy. The firm kept proper documentation and record of the calibrations performed. Records were assessed for inclusion of the following requirements: ....Name of instrument equipment or control ....Date of calibration ....Identity of reference standard with certificate of accuracy ....Identity of calibration method used including limits for accuracy and precision ....Actual calibration reading(s) ....Identity of recal bration method if used ....Actual recalibration reading(s) if used ....Initials of person performing calibration Records contained a l of these items as appropriate.
FE21	Ensure that instruments and controls used in the operation were appropriate in number and adequately maintained for accuracy and precision. §111.27(a)(6)(i-iii)	Acceptable			Instruments and controls used to produce package or hold dietary supplements were evaluated such that they were: - Accurate and precise - Adequately maintained - adequate in number for designated use Those instruments and controls observed during the audit were found to meet the criteria noted above.
FE22	Assess QC operations for equipment, instruments, and controls in relation to ca ibration and qualification processes. §111.117(a-d)	Acceptable			The auditor checked that the Quality operations for equipment instruments and controls included: - Reviewing and approving all calibration processes - Periodically reviewing all calibration records for instruments and controls - Periodically reviewing all records of calibrations inspections and checks of automated mechanical or electronic equipment - Reviewing and approving controls to ensure that automated mechanical or electrical equipment functions as intended QC personnel were appropriately involved in the above listed activities.
FE23	Review the procedures for the compressed air system, if applicable for the firm, and ensure it is not a potential source of contamination. §111.27(a)(7)	Not Applicable			Compressed air is not used in processing components supplements or contact surfaces. It is not a source of contamination.
FE24	Review the firm's methods for protecting against contamination where bulk fermentation vessels are in use. §111.20(g)	Not Applicable			The firm does no processing of supplements in bulk fermentation vessels. 111.20(g) does not apply to this audit.
FE25	Evaluate the firm's documented process for cleaning and sanitizing equipment/utensils. Check that records are kept in logs or in the batch record, with the appropriate sign-offs. §111.25(c) & 111.35(b)(1)(iii)(2)	Acceptable			The firm established documented processes for maintaining cleaning and sanitizing equipment and utensils and other contact surfaces used in the processing of components and supplements. The auditor reviewed the following SOPs: 1) EQPT-3000 - General Equipment Procedures - 6/7/18 2) EQPT-3057 - Utensils - 5/16/19 Records reviewed were kept in individual equipment logs. Logs did contain date of use activity performed product/lot number entries in chronological order QC personnel sign-off. Records of maintenance cleaning and sanitizing were appropriately kept within batch records. Records contained date of use activity performed product/lot number entries in chronological order QC personnel sign-off. The auditor reviewed the following logs/records for cleaning/sanitization maintenance: 1) EQ-04 R2-1 Processing Tank Cleaning Log 2) EQ-24 Grinder-1 Cleaning Log 3) EQ-02 Bottle F ller Cleaning Log 4) EQ-46 Dist ller Mantle 2 5) Batch record pre-line checks and supporting QC approval of cleaning.
FE26	Examine the storage of equipment and utensils for verification that they are protected against contamination. §111.27(d)(7)	Acceptable			Cleaned and Sanitized portable equipment and utensils in use in the firm were found to be properly stored to protect against contamination. The auditor reviewed the following cleaning records/labeling for verification of cleaning and sanitization: 1) EQPT-3000 - General Equipment Procedures - 6/6/18 2) EQPT-3057 - Utensils - 5/16/19 The firm established the length of time during which a cleaned piece of equipment is still deemed acceptable for use without recleaning.
FE27	Confirm that equipment and utensils were taken apart where necessary for thorough cleaning and maintenance. §111.27(d)(1)	Acceptable			Where necessary equipment and utensils were found to be taken apart for thorough maintenance cleaning and sanitizing. The auditor reviewed the following cleaning records for ver fication of cleaning and sanitization: 1) EQ-04 R2-1 Processing Tank Cleaning Log 2) EQ-24 Grinder-1 Cleaning Log 3) EQ-02 Bottle F ller Cleaning Log

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FE28	Where single service articles were used, verify they were handled, stored and disposed of such that the risk of contamination was minimized. §111.27(d)(5) (i-ii)	Acceptable			Where single-service utensils were used they were stored appropriately. They were handled dispensed used and disposed of in a manner that protected against contamination.
FE29	Ensure that surfaces that do not come into direct contact with components and dietary supplements cleaned as frequently as necessary to prevent contamination. §111.27(d)(4)	Acceptable			Where surfaces did not come into direct contact with components or supplements they were noted to be cleaned at a frequency that protected against contamination. The auditor reviewed the following cleaning records for ver fication of cleaning and sanitization: 1) Daily Cleaning and Maintenance Check list Jan-May 2019 - Production Room Cook Area 2) Daily Cleaning and Maintenance Check list Jan-May 2019 - Production Room Filling Area
FE30	Verify that the firm maintains records for cleaning, maintenance, and sanitization, and these logs contain the appropriate information and second-person verification. NPA.C.4.1	Acceptable			There are individual written maintenance cleaning sanitizing and use logs for processing rooms and areas. The logs contained the date activity performed product lot number and second person verification of each batch processed in the individual room/area observed. The auditor reviewed the following records: 1) Daily Cleaning and Maintenance Check list Jan-May 2019 - Production Room Cook Area 2) Daily Cleaning and Maintenance Check list Jan-May 2019 - Production Room Filling Area
FE31	If the firm performed wet processing, confirm contact surfaces were cleaned as required to prevent contamination. §111.27(d)(3)	Acceptable			Where wet processing was done contact surfaces were clean and sanitized to protect against introduction of microorganisms. The auditor reviewed the following cleaning records for ver fication of cleaning and sanitization: 1) EQ-04 R2-1 Processing Tank Cleaning Log 2) EQ-02 Bottle F ller Cleaning Log
FE32	Review cleaning compounds and sanitizing agents and ensure they are safe and adequate for use. §111.15(c)(1) Check that these items are being stored and identified to protect against contamination. §111.15(c)(1,3)	Unacceptable	Minor	CAR-1	There was documentation outlining the types of cleaners and sanitizers to be used in the cleaning of the facility and equipment. WI/SOP reviewed: PHYS-2003 - Approved Chemicals - 6/8/18 Cleaning compounds and sanitizing agents were not established as being free from microorganisms of public health significance and were deemed safe and adequate under conditions of use. Cleaners reviewed: 1) Jolt 2) Pine Sol Cleaning compounds and sanitizing agents were identified and held in a manner that protects against contamination. Nonconformance Noted: The approved chemical list is not complete as it does not include all the chemicals observed in the facility; i.e. Windex and does not include all the chemicals maintained in the MSDS binder; i.e. Simple Green All Purpose Cleaner and others. In addition there is no MSDS on file for Clorox or Dawn Pot & Pan Detergent currently in use.
FE33	Toxic materials are only permitted for use if deemed necessary in cleaning and sanitization, in laboratory testing, or in maintenance and operation of equipment. Ensure such toxic materials are not used in any other capacity, and that any toxic material is properly controlled and stored. §111.15(c)(2)(i-iv)	Not Applicable			There was no toxic material noted to be in use at the firm.
	Material System				
MS1	Review the firm's procedures for receipt, examination and quarantine. §111.153 & §111.180(b)(1)	Acceptable			The auditor reviewed procedures describing the receipt and inspection of components and/or packaging and labeling. SOP: QAQC-4001 - Receiving - 9/8/17
MS2	Inspect the firm's activities for receipt of components and verify that items are properly examined before use. §111.155(a)(b); 111.180(a)(b)(2); 111.120(a)	Acceptable			When receiving components the firm examined the immediate container closure system for appropriate content label container damage or broken seals to ensure they were unaffected by contamination or deterioration. They did examine (or test) for filth insect infestation and/or other visually evident extraneous matters as necessary. Personnel inspected the supplier's invoice guarantee or cert ficate of the shipment to ensure components were consistent with the purchase order. QC personnel were noted as reviewing receiving records for components. Records of these examinations were kept. Record: Receiving form lot 18-0815 12/19/18 Record: Receiving form lot 18-0835 12/27/18

	Requirement	Acceptable?	NC Type	CAR Number	Comment
MS3	Inspect the firm's activities for receipt of packaging and labeling, and verify that items are quarantined as appropriate and properly examined before use. §111.160(a)(b), 111.75(f), 111.120(a)	Acceptable			When receiving packaging/labels the firm examined the immediate container closure system for appropriate content label container damage or broken seals to ensure they were unaffected by contamination or deterioration. Personnel inspected the supplier's invoice guarantee or cert ficate of the shipment to ensure packaging and labels were consistent with the purchase order. QC personnel were noted as reviewing receiving records for packaging/labe ing. Records of these examinations were kept. Record: Receiving Form lot 042619-03-LK Record: Receiving Form lot LK-02710
MS4	Where containers of bulk product are received for packaging or labeling as a dietary supplement (and for distribution rather than for return to supplier) verify that items received are quarantined as appropriate and properly examined before use. §111.165(a)(b), 111.75(e)	Not Applicable			The Firm did not perform packaging/labeling of received finished dietary supplements for distribution (rather than return to the supplier). The requirements for incoming inspection as specified in 111.165(a)(b) do not apply.
MS5	Verify that the firm is conducting an examination of finished product to ensure the correct packaging and labeling was applied before shipping. §111.75(g)	Acceptable			Finished product was properly examined to ensure the correct packaging and labeling was applied.
MS6	Check holding and receiving records for inclusion of the necessary information. §111.180(b)(3)(i)(A-D)	Acceptable			The auditor confirmed confirm that observed personnel performing activities involved with receipt were documenting the activity *at the time of its performance.* The records sampled for conformance to receiving requirements were reviewed for completeness in terms of containing the following items: - The date of receipt; - The initials of the person performing the required operation; - The results of any tests or examinations conducted; and - Any material review and disposition decision conducted. These items were included in the records sampled.
MS7	Sample incoming lots of components and packaging/labels to check that a unique identifier is assigned for traceability purposes. §111.155(d), 111.160(d), NPA.G.1.2	Acceptable			The firm identified each unique lot of components sampled by the auditor such that there was traceability to the supplier the date received the name of the component the status of the component and traceability to the supplement manufactured and distributed. The unique identifier for each lot was also on the container of each component received or produced. The unique identifier was used when recording the disposition of the lot. Unique ID: Lot #051719-07-MBS Unique ID: Lot #050619-07 The firm identified each unique lot of packaging and labels sampled by the auditor such that there was traceability to the supplier the date received the name and status of the packaging and label and traceability to the supplement distributed. The unique identifier was used when recording the disposition of the lot. Unique ID: Lot #B02683 Unique ID: Lot #B02678
MS8	Sample incoming lots of dietary supplement sent to the firm for packaging and distribution to check that a unique identifier is assigned for traceabi ity purposes. §111.165(d)(1)	Not Applicable			The Firm did not perform packaging/labeling of received finished dietary supplements for distribution (rather than return to the supplier). The requirements for quarantine and sampling as spec fied in 111.165(c) do not apply.
MS9	Inspect the firm's activities for receipt of components and verify that items are quarantined as appropriate. §111.155(c)	Acceptable			The firm quarantined components from use in the process until a representative sample had been taken and QC personnel performed the required actions. Components were held in quarantine in a manner that protected against contamination. Record of QA review and approval: Item #TIB0164 lot 18-0655 Record of Quarantine product reviewed: none There were no components in quarantine to review for practices. However the procedure reviewed confirmed that components would be quarantined from use in the process until a representative sample had been taken and QC personnel performed the required actions.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
MS10	Review the firm's activities for receipt of Packaging and labelling and verify that items are quarantined as appropriate. §111.160(c)	Acceptable			The firm quarantined packaging and labeling from use in the process until a representative sample had been taken and QC personnel performed the required actions. Packaging and labeling was held in quarantine in a manner that protected against contamination. Record of QA review and approval: Packaging Component Release Form Item #WGD1 lot BR-02785 Record of Quarantine product reviewed: none There was no packaging/labeling in quarantine to review for practices. However the procedure reviewed confirmed that packaging and labeling would be quarantined from use in the process until a representative sample had been taken and QC personnel performed the required actions.
MS11	Review the firm's activities for receipt of finished supplements for packaging/labeling, and verify that items are quarantined as appropriate. §111.165(c)	Not Applicable			The Firm did not perform packaging/labeling of received finished dietary supplements for distribution (rather than return to the supplier). The requirements for quarantine and sampling as spec fied in 111.165(c) do not apply.
MS12	Review rejected components, packaging and labeling, and bulk product that has been deemed unsuitable for use, to verify that it is identified and held under quarantine for appropriate disposition. §111.170	Acceptable			Rejected materials packaging or products were properly held under a quarantine system for disposition. Record(s) reviewed: 1: Raw Material Identification and Release Cover Sheet item #MGR024 lot 19-0142 rejected on 3/21/19
MS13	Evaluate the firm's program for collecting representative samples and indicate if QC has adequate oversight over the activities. §111.80(a-e)	Acceptable			There were proper representative samples taken of each unique lot of components. There were representative samples taken for packaging and labeling specifications. Regarding in-process samples these were taken for each batch at points specified in the MMR where control is necessary to ensure product efficacy. Quality Control personnel did ensure the above required representative samples were collected. SOPs reviewed for sample collection: 1: QAQC-4024 - Sampling for Testing - 3/4/19
MS14	Ensure a representative sample from each batch of packaged and labeled dietary supplement is examined to determine if the dietary supplement meets specifications established under 111.70(g). §111.415(g)	Acceptable			The firm took a representative sample from each batch of packaged and labeled dietary supplement to determine if the finished dietary supplement meets specifications established under §111.70(g). Samples verified: 1. lot #12851 2. lot #12783
MS15	Evaluate the conditions under which components and supplements are held to protect identity, purity, strength, and composition. §111.455(a)(b)(c), 111.460(a)(b), 111.453	Acceptable			There are written procedures (i.e. SOPs) that describe the practices for the holding of components in-process materials dietary supplements packaging and labels under appropriate conditions of temperature humidity and light so they are not adversely affected. SOP: QAQC-4030 - Monitoring Temperature and Relative Humidity - 6/8/18 Components and supplements were held under appropriate conditions of temperature humidity and light. Packaging and labeling were held under conditions so that they are not adversely affected. Components packaging labeling and final product were held under conditions to protect against mix-up contamination or deterioration. Inprocess materials were held under appropriate conditions of temperature humidity and light and in such a way as to protect against contamination or mix-up.
MS16	Ensure bulk product received for packaging or labeling as a dietary supplement is held under conditions that protect against contamination, deterioration and mix-ups. §111.165 (e)	Not Applicable			The Firm did not perform packaging/labeling of received finished dietary supplements for distribution (rather than return to the supplier). The requirements for quarantine and sampling as spec fied in 111.165(c) do not apply.
MS17	Ensure the firm is using the FIFO system for processing incoming components. NPA.G.1.3	Acceptable			Raw material and packaging components approved and released for use are rotated so that the oldest stock is used first (FIFO).
MS18	Check that components are retested or reexamined after a specified time in storage or after exposure to adverse conditions to ensure the components continue to meet their established specifications. NPA.G.1.4	Not Applicable			Raw materials are returned to the customer after a production run. There are no raw materials that are stored long term that require retest or reexamination after a specified time in storage or after exposure to adverse conditions to ensure the raw material continues to meet established spec fications.
MS19	If cold storage is in use at the firm, verify that there are procedures governing their control, and that the proper monitoring equipment is in use. §111.27(a)(5)(i,i); 111.365(h)(2)	Acceptable			There were written procedures (i.e. SOPs) describing the monitoring of freezers and cold-storage compartments in production and control areas. The auditor reviewed the following SOPs: 1) QAQC-4030 - Monitoring Temperature and Relative Humidity - 6/8/18 Cold storage compartments in use in the firm (including freezers and refrigerators) were checked for the following: -The proper use of a temperature-monitoring device that indicates and records or allows hand-recording of the temperature of the compartment - The use of an automated temperature regulating device or an alarm system to indicate significant temperature change. Cold storage areas met these requirements.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
MS20	Where water is used as a supplement, or in a supplement contact manner, verify the water has been tested to ensure its suitability and that it does not pose a threat of contamination. §111.15(e)(2), 111.365(c)	Acceptable			For water used as a component (DI RO or PW) or where such water may contact components or supplements there was data verifying that such water complied with USP requirements and that it did not pose a contamination threat to dietary supplements. Review of water system data: Microbial: Quarterly - 8/22/18 12/3/18 3/4/19 TOC: not tested Conductivity/Resistivity: not tested Facility tests for Total Dissolved Solids on a monthly basis. Jan-May 2019 results are 0 and 1 and indicate system is maintained . The firm had a procedure related to the water system with regard to maintenance sanitization testing and sampling. SOP: QAQC-4020 - Water Testing - 3/4/19 SOP: EQPT-3079 - Equipment: EQ-79 2Ppure The firm had records related to sanitization and maintenance of the water system an Records reviewed for maintenance and sanitization: 1: Monthly filter replacement records - Jan-April 2019
MS21	Ensure dietary supplements are distributed under conditions that protect against contamination and deterioration. §111.470, 111.475 (a) (b)	Acceptable			The company had written procedures (i.e. SOPs) for the distribution of dietary supplements. SOP's reviewed: SOP: QAQC-4040 - Shipping - 6/20/18 Dietary supplements were held and distributed under conditions that protect against contamination and deterioration. The firm maintained distribution records. Distribution Record: Invoice #10531 Distribution Record: Invoice #10451
	Production System				
PS1	Check the firm's procedures for creating Master Manufacturing Records, and ensure that Quality personnel review and approve MMR's. §111.123(a)(1); NPA.H.1.1	Unacceptable	Minor	CAR-2	The firm had written procedures (SOPs) that describe the preparation review approval and revision of master manufacturing records. SOP: QAQC-4006 - Master Manufacturing Records - 6/8/18 The MMR at the firm were not reviewed and approved by Qua ity personnel. Any modifications to the MMR were not reviewed and approved by QC Personnel. MMR record: [redacted]-0004-55-J-FNL MMR record: [redacted]-0005-54-A1-FNL MMR record: LK-0002-97.2-A-V1-FNL Nonconformance Noted: MMRs exist for all formulas and batch sizes and are reviewed by Quality; however there is no documentation of Quality approval.
PS2	Review the firm's master manufacturing records for product and indicate whether or not it contained the required information and if it was reviewed by Quality Personnel. Ensure there was a written procedure governing this process. §111.205(a)(b)(1-2)(c); 111.55	Acceptable			The firm maintained a master manufacturing record for each formulation and/or batch size to ensure uniformity of product from batch to batch. The MMR contained specifications for the process where control is necessary to ensure quality and that the product is produced as specified. The MMR established controls and procedures that ensure the supplement met those specifications.
PS3	Check that the firm's Master Manufacturing Records contained all required items under 111.210(a-g).	Acceptable			The auditor reviewed an MMR to ascertain if it included the following required items under 111.210: ....The name of the dietary supplement to be manufactured ....The strength concentration weight or measure of each dietary ingredient for each batch size ....A complete list of components to be used ....The identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label ....The identity of each ingredient that will be declared on the ingredient list of the dietary supplement ....A statement of any intentional overage amount of a dietary ingredient ....A statement of theoretical yield expected at each point step or stage where control is needed to ensure quality ....The expected yield when you finish manufacturing including the maximum and minimum percentages of theoretical yield beyond on which a deviation investigation of a batch is necessary and a material review and disposition decision is made ....A description of packaging ....A representative label or a cross-reference to the physical location of the actual or representative label The MMR reviewed recorded the items noted above.
PS4	Confirm that the MMR contains all the written instructions necessary for the process. §111.210(h)(1-5)	Acceptable			The firm's MMR also contained written instructions for processing as specified in 111.210(h). Namely instruction is required to include: ....Specifications for each point step or stage where control is needed to ensure qua ity ....Procedures for sampling ....Cross-reference to tests or examinations ....Specific actions to perform and verify points steps or stages where control is needed to ensure quality ....Specific actions to verify the weight or measure of any component ....Specific actions to verify the addition of any component ....For manual operations specific actions include one person for weighing and one person ver fying the weight of each component ....For manual operations specific actions include one person for adding the component and one person verifying the addition ....Special notations and precautions to be followed ....Corrective action plans for use when a specification is not met Instructions reviewed in the MMR contained all of the above listed items.
PS5	Verify the firm maintains procedures covering the issuance of batch production records. NPA.I.1	Unacceptable	Minor	CAR-3	The company did not have written procedures (SOPs) that describe the issuance of batch production records that verify it is a facsimile of the master manufacturing record. SOP: QAQC-4007 - Batch Production Record - 5/20/19 Nonconformance Noted: SOP QAQC-4007 does not describe the issuance of batch production records and the process to verify it is a facsimile of the master manufacturing record.

#	Requirement	Acceptable?	NC Type	CAR Number	Comment
PS6	Ensure the firm maintains procedures on issuance of batch records, and that batch records are created for every batch of supplement processed. §111.255(a,b,c) NPA.I.1.1	Acceptable			For every batch of dietary supplement processed the firm did prepare a batch record. The record was found to fo low the appropriate MMR. Batch Record: [redacted] 0004-55-J-FNL lot 12755 12/21/18 Batch Record: [redacted] -0005-54-A1-FNL lot 12783 1/29/19 Batch Record: LK-0002-97.2-A-V1-FNL LOT 12851 4/16/19
PS7	Indicate whether or not batch records conta ned all of the items noted in 111.260, parts a - h. §111.260(a-i)	Acceptable			The batch record reviewed included complete information relating to the production and control of the batch. The following items were checked: ....The batch lot or control number of the finished batch ....The batch lot or control number assigned to each lot of packaged and label dietary supplement from the finished batch ....The batch lot or control number assigned to each lot of dietary supplement from the finished batch that is distributed to another person for packaging or labeling ....The identity of equipment and processing lines used ....The date and time of the maintenance cleaning and sanitizing of the equipment and processing lines used or a cross-reference to records where this information is stored ....The unique identifier assigned to each component packaging and label used (or the unique identifier for the bulk product received for packaging and labeling) ....The identity and weight or measure of each component used ....A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases ....The actual results obtained during any monitoring operations ....The results of any testing or examination performed during the batch production or a cross-reference to the such results ....Documentation that the finished product meets spec fications established under §111.70(e)&(g)
PS8	Verify the batch records contain the date on which the steps are performed and the initials of the person performing the step. §111.260(j)	Acceptable			Batch production records included the date on which each step was performed. They contained the initials of each person performing each step.
PS9	Indicate whether or not batch records contained all of the items noted in 111.260, parts k and l §111.260(k)(1-3)	Acceptable			The batch record contained all of the following as appropriate in regards to packaging and labeling: ....The unique identifier assigned to the packaging and labels used ....Reconci iation of discrepancies between issuance and use of labels (when applicable) ....An actual or representative label (or cross-reference to the location of an actual or representative label) specified in the master manufacturing record ....Results of any tests or examinations conducted on packaged and labeled product (including repackaged or relabeled products) or cross-reference to the results
PS10	Indicate whether or not batch records contained all of the items noted in 111.260, part l	Acceptable			Batch production records contained appropriate QC personnel signoff as applicable for reviewing the batch record and final disposition.
PS11	Check that the firm is monitoring in-process points, steps, or stages where control is necessary to ensure the quality of the finished dietary supplement. §111.75(b)(1,2)	Acceptable			The firm was monitoring in-process steps where control was necessary for ensuring the quality of the finished supplement and to ensure that in-process specifications were being met. Evidence reviewed for in-process specifications: 1: Quality approval of the Finished Product Examination Page - lot 12755 12783 and 12851. The firm took action to detect any deviation or unanticipated occurrence that may result in a failure to meet in-process specifications. Evidence reviewed for in-process specification deviations: 1: Deviation log 2: Deviation Form for lot 12612
PS12	Ensure there is appropriate documentation of material review and disposition decisions, and that the records encompass the required information. §111.140(b)(3)(i-vii)	Acceptable			The company does have written documentation of any material review and disposition decisions and follow-up. The material review was kept in the appropriate batch record. Records sampled for material review and disposition were assessed for containing the following required items: - Identification of the specific deviation or unanticipated occurrence; - Description of investigation into the cause - Evaluation of whether or not the deviation has resulted in or could lead to a failure to ensure the quality of the supplement or a failure to package and label the dietary supplement as specified in the master manufacturing record; - Identification of the action(s) taken to correct and prevent a recurrence of the deviation or the unanticipated occurrence; - Explanation of what was done with the component dietary supplement packaging or label; - The signature of the individual(s) designated to perform the quality control operation who conducted the material review and made the disposition decision and of each qualified individual who provided information relevant to that material review and disposition decision The auditor confirmed that documentation met the above criteria.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
PS13	Verify there are written procedures (i.e., SOPs) that ensure all processing lines, major equipment and containers used during manufacturing are identified to indicate their contents. §111.365(k), §111.365(j) & §111.353 & §111.375(b)	Acceptable			The auditor found that the firm ensured that processing lines and major equipment used during manufacturing are identified to indicate their contents including: - Name of dietary supplement - Specific batch or lot number - Phase of manufacturing (when necessary) The firm ensured that all containers for a specific batch of dietary supplements are identified and segregated to identify their contents and where necessary indicate the phase of manufacturing. SOP's reviewed: SOP: EQPT-0002 - EQ-02: Bottle Filler - 5/15/19 SOP: EQPT-0004 - EQ-04: R2 - 1 Processing Tank - 5/15/19 Samples reviewed by the auditor to ensure proper identification of equipment and lines: Sample: Bottle Fill line Sample: Mixing area Containers with lot numbers of supplements verified by the auditor to be properly identified and segregated: Sample: [redacted] lot 12742 Sample: Vanilla Stevia lot 12878
PS14	Establish that there are written procedures that define the precautions the firm has taken to remove, destroy, or prevent the growth of microorganisms and prevent decomposition. §111.365(e) & §111.353	Acceptable			The company does written procedures (i.e. SOPs) to ensure all necessary precautions are taken during manufacturing to prevent contamination of components or dietary supplements including: ....Sterilizing pasteurizing freezing refrigerating controlling hydrogen-ion concentration (pH) controlling humidity controlling water activity (aw) or using other effective means to remove destroy or prevent the growth of microorganisms and prevent decomposition SOP's reviewed: SOP: QAQC-4021 - Contamination Statement - 5/20/19 SOP: QAQC-4033 - Control of Foreign Material - 3/13/18 SOP: QAQC-4031 - Critical Control Points - 5/20/19
PS15	Verify there are written procedures (i.e., SOPs) that ensure that mechanical manufacturing steps (i.e., cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) are performed in a manner that protects against contamination. §111.365(h)(1-3) & §111.353 & §111.375(b)	Acceptable			The firm had written procedures that ensure that mechanical manufacturing steps are performed in a manner that protects against contamination including: ....Cleaning and sanitizing contact surfaces ....Using temperature controls ....Using time controls SOP's reviewed: SOP: QAQC-4021 - Contamination Statement - 5/20/19 SOP: QAQC-4033 - Control of Foreign Material - 3/13/18 SOP: QAQC-4031 - Critical Control Points - 5/20/19
PS16	Verify there are written procedures (i.e., SOPs) that ensure effective measures are used to protect against the inclusion of metal or other foreign material in components, in-process materials, or dietary supplements. §111.365(i)(1-4) & §111.353 & §111.375(b)	Acceptable			The company does have written procedures (i.e. SOPs) and processes to ensure effective measures are used to protect against the inclusion of metal or other foreign material in components in-process materials or dietary supplements including: - Using filters or strainers - Using traps - Using magnets - Using electronic metal detectors - Screens - x-ray SOP's reviewed: SOP: QAQC-4021 - Contamination Statement - 12/27/18 Equipment onsite used to detect foreign material: - micron screens - felt press bag
	Packaging System				
PA1	Review the Firm's written procedures (i.e., SOPs) for the packaging and labeling operations. §111.403 & §111.430(a,b)	Acceptable			There were written procedures governing the packaging and labeling operations. The procedures were assessed for inclusion of the following: ....Confirming packaging and label specifications ....Control of the issuance and use of packaging and labels ....Reconci iation of issuance and use discrepancies ....Examining packaging and labels before use to determine conformance to the master manufacturing record ....Determining the complete manufacturing history ....Control of the packaged and labeled dietary supplement through distribution The procedure included a l of the above required items. SOP's reviewed: SOP: QAQC-4012 - Labels - 5/7/18 SOP: QAQC-4027 - Packaging - 5/20/19
PA2	Indicate whether or not personnel were following procedures for issuance and reconciliation, and that packaging and labels were examined before being used, in accordance with the MMR. §111.410(b,c,d)	Unacceptable	Minor	CAR-4	The firm controlled the issuance and use of packaging and labels. The firm did not perform reconciliation of any issuance and use discrepancies. The firm examined packaging and labels *before* performing the operation in order to ensure they conform to the MMR. The auditor could determine the complete manufacturing history and control of the sampled dietary supplement through distribution. Nonconformance Noted: Primary bottle labels are properly reconciled however secondary retail cartons are not reconciled.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
PA3	Check that f lling, assembling, packaging, labeling and other related operations are performed in a way that ensures the quality of the dietary supplement and that the product is packaged and labeled as specified in the master manufacturing record. §111.415(a-e); 111.403; 111.430(a,b)	Acceptable			The firm's packaging and labeling operations were evaluated to ensure that activities effectively maintained the quality of the supplement including: ....Cleaning and sanitizing all filling and packaging equipment utensils and packaging as appropriate ....Protecting manufactured dietary supplements from contamination (particularly airborne contamination) ....Using sanitary hand ing procedures ....Establishing physical or spatial barriers separation of packaging and labeling operations from other operations to prevent mix-ups ....Identifying by any effective means fi led dietary supplement containers that are set aside and held in an unlabeled condition for future labeling to prevent mix-ups The firm was noted as performing all of the above actions as necessary. These items were covered in a procedure governing the packaging/labeling operation. SOP: QAQC-4027 - Packaging - 5/20/19 SOP: EQ-02: Bottle Filler - 5/15/19
PA4	Verify that finished dietary supplements are given a unique batch, lot or control number as appropriate. §111.415(f)(1-2)	Acceptable			A batch lot or control number was assigned to: ....Each lot of packaged and label dietary supplement from a finished batch ....Each lot of dietary supplement, from a finished batch, that is distributed for packaging and labeling The unique control number was available on the immediate container and the retail container and was visible and readable by the consumer.
PA5	Indicate whether obsolete or incorrect labels and packaging are suitably disposed of to ensure they are not used in future packaging and label operations. §111.415(h)	Acceptable			Labels and packaging that were obsolete or incorrect were disposed of such that they would not be used in any future packaging or labeling operations.
PA6	If the firm performs repackaging or relabeling of product, verify that representative samples of each batch are examined to determine if they meet all specifications established under §111.70(g). §111.420(a)(b)	Acceptable			Where repackaging or relabeling was possible this was done only after Quality personnel approved such activities. A representative sample of the batch was examined to determine whether or not the repackaging or relabeling operation was successful. Quality control personnel were the final say on distribution of repackaged or relabeled product.
	Laboratory System				
LS1	Confirm there are written procedures available that govern the laboratory processes at the firm. §111.303; 111.315(a)(b)(1-5)(c)(d)(e), 111.110(a)	Acceptable			There were written procedures governing laboratory operations. The procedures were reviewed to ensure there were established processes for: - Use of the criteria for establishing specifications - Use of samp ing plans for obtaining representative samples for testing - Use of criteria for selecting appropriate examination and testing methods - Use of criteria for selecting standard reference materials - Use of test methods and examinations in accordance with established criteria The auditor confirmed written processes for all of these items. SOP: GENL-0005 - Reference Materials and Archives - 5/14/19 SOP: QAQC-4009 - Samples - 5/20/19 SOP: QAQC-4018 - Specification Establishment - 2/4/19 SOP: QAQC- 4024 Appendix A - Sampling for Testing - 3/4/19 Lab processes were reviewed and approved by Quality Control personnel.
LS2	Indicate whether laboratory facilities were adequate to allow the firm to perform the necessary activities. §111.310(a-c)	Acceptable			The auditor ver fied the laboratory facilities were adequate to perform required testing and examinations for components in-processing and final products as applicable.
LS3	Analyze the specifications that have been established for the components of dietary supplements. This should include specifications for identity, limits on contaminates, and other specifications that prove that purity, strength and composition of the supplement are met. §111.70(b)(1-3), 111.95(b), 111.365(d)	Unacceptable	Minor	CAR-5	For components used in the manufacture of the supplements the auditor confirmed that there were established specifications supported by appropriate documentation. These included specifications to establish identity. There were component specifications that ensured the expectations for purity strength and composition of dietary supplements were met. Furthermore component specifications included limits on types of contaminates that may adulterate or lead to adulteration of finished batches of supplement product. The auditor reviewed the following specifications: 1) Raw Material Identification and Release Cover Sheet item #TIB0164 2) Raw Material Identification and Release Cover Sheet item #GLY 3) Raw Material Identification and Release Cover Sheet item #LKCTOCOL **Nonconformance Noted**: The component specifications (Raw Material Identification and Release Cover Sheet) are not revision controlled or approved by Quality.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
LS4	Confirm that in-process specifications have been established for each point, step, or stage in the master manufacturing record where control is needed to ensure specifications for identity, purity, strength, composition and limits on contaminants are met. §111.70(c)(1-2); 111.95(b)	Acceptable			The auditor found that specifications for in-process steps were established for points where control was necessary to ensure the expectations for identity purity strength and composition of the dietary supplement were met. Specifications reviewed: 1) LK-0002-97.2-A-V1-FNL 2) [redacted] 54-A1-FNL 3) [redacted]-0004-55-J-FNL lot 12755 The in-process specifications reviewed by the auditor were traceable to the documented rationale on how such specifications in conjunction with component specifications will ensure the quality and safety of the dietary supplement. 1) In-process specifications: ingredient item # verification ingredient weights decoction cook time/temp organoleptic properties pH specific gravity bottle fill volume
LS5	Ensure that specifications have been established for dietary supplement labels and packaging that may come into contact with dietary supplements. §111.70(d)	Unacceptable	Minor	CAR-6	Specifications for labels were not established. Label Specs reviewed: 1: There are no label specifications The firm established specifications for packaging that comes into contact with dietary supplements ensuring that it is safe and suitable for intended use. Packaging specs reviewed: 1: Packaging Component Release Form item #WGD1 2: Packaging Component Release Form item #LK2WAF Nonconformance Noted: There are no label specifications. The packaging specifications (Packaging Component Release Form) are not revision controlled or approved by Quality.
LS6	For finished Dietary Supplements, establish that specifications have been developed for identity, purity, strength and composition, and that this includes limits on potential contaminates. §111.70 (e)	Acceptable			Specifications have been established for the identity purity strength and composition of the finished batch for each dietary supplement the company manufactures. Limits on contaminants or potential contaminants have been established for finished dietary supplements. Examples of finished product specifications reviewed: 1: Focus approved 4/30/19 2: Pau D' Arco (no quality signature/date) 3: DHEA approved 6/5/18
LS7	In regards to labeling of finished product, confirm that the firm has developed specifications that ensure the specified packaging and labeling were used. §111.70(g)	Acceptable			Specifications have been established for the packaging and labeling of the finished product that ensure the specified packaging and labeling were used. Examples of components and label specifications reviewed: (Note: The finished product specifications reviewed contained the packaging and labeling requirements.) 1: Focus approved 4/30/19 2: Pau D' Arco (no quality signature/date) 3: DHEA approved 6/5/18
LS8	If the firm receives dietary supplement products from a supplier for packaging and labeling, verify that specifications have been developed that provide sufficient assurance the product received is sufficiently identified and is consistent with the purchase order. §111.70(f)	Not Applicable			The firm did not receive product from a supplier for packaging/labeling that was later distributed by the firm. 111.70(f) is not applicable to this operation.
LS9	Regarding the above established specifications, verify that QC personnel have reviewed and approved them, and that they have documented the basis for why the specifications are relevant to the quality of the product. §111.105(a)(c)(d)	Acceptable			QC personnel does review and approve or reject specifications developed by the firm. QC does review and approve the documentation that sets forth the basis for: - why meeting the in-process spec fications and component specifications will ensure the efficacy of the process - why the results of final product tests/examinations will ensure the supplement meets specifications
LS10	Analyze the testing done on dietary ingredient components. If the firm has noted exemptions, check that it was approved by the FDA. 111.75(a)(1)	Acceptable			For Dietary ingredient components testing to verify identity was being done by QA in accordance with the established specifications. Exemptions granted by the FDA were reviewed by the auditor. The firm was noted as following the terms specified by the FDA in the granting of the exemption. Components Reviewed for verification of identity testing: Component 1: item #SCHPE9BA lot 18-0851 Testing performed: Organoleptic (flavor aroma appearance) HPTLC visual analysis of extraneous matter Component 2: item #LKCTCOL LOT 18-0725 Testing performed: Organoleptic (flavor aroma appearance) macroscopic HPLC assay visual analysis of extraneous matter Component 3: item # TIB0164 lot 18-0655 Testing performed: Organoleptic (flavor aroma appearance) macroscopic particle size visual analysis of extraneous matter

	Requirement	Acceptable?	NC Type	CAR Number	Comment
LS11	For other components, confirm that testing has been done to establish that specifications were met. 111.75(a)(2)(i)	Unacceptable	Minor	CAR-7	For other components the auditor checked to ensure that appropriate tests/examinations were being done by QA. They were not noted as being properly completed as applicable. The firm relied solely on Certificate of Analysis for other components. Components Reviewed for verification of limits of contamination testing: Component 1: item # LKNM BF lot 18-0768 Testing performed: no testing; CoA review only Component 2: item #GLY lot 19-0179 Testing performed: specific gravity appearance taste odor Nonconformance noted: Identity testing is not completed on all batches of excipient components (defined by faci ity as non-herbal adjunctive materials such as flavors and preservatives). Glycerin identity is confirmed annually; however the flavor and glycerin batch reviewed were not tested for identity.
LS12	Where a Certificate of Analysis was used for non-ingredient components, ensure the firm has taken the necessary steps to verify the CoA and periodically reconfirm it. §111.75(a)(2)(ii)	Acceptable			Where CoA was used to confirm components the firm's use of the CoA was assessed in accordance with the following: - The reliability of the CoA is established through confirmation of the results of the supplier's tests/examinations. - The CoA includes a description of the tests/examination methods used the limits of such tests/examinations and actual results thereof. - There is documented support for the qualification of the supplier from which the CoA was received. - There is documented evidence of the review and approval of supplier qualification and requalification by QA - The CoA is periodically reconfirmed. The records reviewed for CoA acceptance of components met all of the above noted requirements. SOP(s) reviewed for Supplier Qualification: SOP 1: QAQC-4008 - Vendor Qualification Program - 3/4/19 SOP 2: QAQC-4041 - Foreign Supplier Verification Program - 3/4/19 Evidence reviewed for the Qualification of Suppliers (including QA approval): 1: [redacted] Hericium erinaceous lots 16-0157 and 17-093 2: [redacted] extract lots 12-0464 12-0465 and 12-0466 Evidence of periodic reconfirmation of COA results: 1: Hericium erinaceous lot 18-0214 2: [redacted] extract lots 17-0041 18-0587 and 19-0165
LS13	Verify that the firm is testing finished product batches appropriately against final product specifications, using a sound statistical sampling plan. §111.75(c)(1-4) 111.80(c)	Acceptable			The firm was taking a subset of finished dietary supplement batches for final product testing. This subset was selected through a sound statistical sampling plan. SOP reviewed for the sampling of finished product: SOP#: QAQC-4019 - Finished Product Testing -5/20/19 SOP#: QAQC-4024 -Sampling for Testing - 3/4/19
		Acceptable			Regarding finishing product testing performed at the firm the auditor sampled results for verification that the final product met all expected specifications. The following criteria was used in this evaluation: - one or more of the established specifications is selected that when tested verifies that the production and process control system in place is capable of producing a supplement that meets specifications - appropriate tests/examinations are performed to determine the compliance of the product to the above chosen specification. - Adequate documentation was retained as to the basis for determining compliance - Documentation provided is reviewed and approved by QC personnel. The firm's final product testing program was noted to meet all of the criteria listed above in the samples reviewed by the auditor. Evidence reviewed for final product testing: Lot #1: 12755 Visual odor flavor specific gravity pH Lot #2: 12783 Visual odor flavor pH density Lot #3: 12851 Identity appearance aroma flavor pH density gluten heavy metals microbiological testing carbohydrate calories
LS14	If the firm exempted specifications, confirm that such exemptions were confirmed to have no scientifically valid test methods by reviewing the firm's documented rationale. 111.75(d)(1-2)	Not Applicable			The firm did not exempt any final product specification testing under 211.75(d)(1).

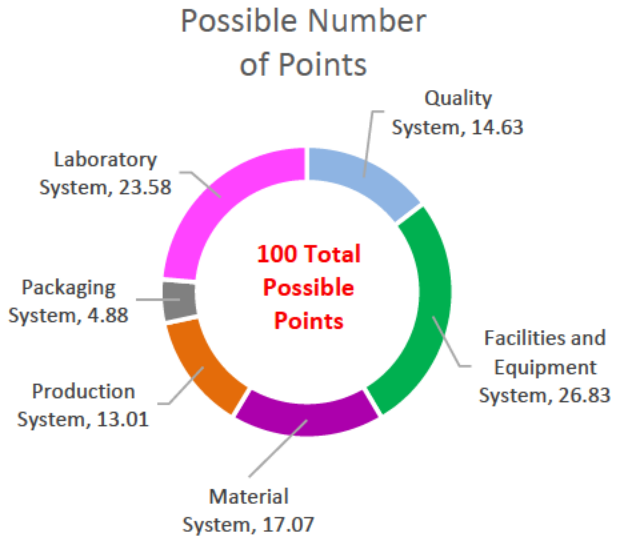
	Requirement	Acceptable?	NC Type	CAR Number	Comment
LS15	Analyze the firm's program for finished product reserve samples to ensure it meets requirements. §111.83(a)(b)(1-4); 111.465(a)(1-2)(b)	Acceptable			There is documentation describing the instructions for collecting and holding reserve samples. SOP: QAQC-4009 - Samples - 5/20/19 The firm was holding reserve samples of each lot of supplements distributed. Reserve samples Reviewed: 1: UPC 814542000073 lot 10938 exp 9/17 2: UPC 816907011205 lot 10831 exp 5/17 The auditor reviewed the firm's program for holding reserve samples based on the following regulatory requirements: - Samples are protected against contamination and deterioration - Samples are held using the same container-closure system or a container-closure system with essentially the same characteristics; - Samples are identified with the batch lot or control number; - Samples are retained for 1 year past the shelf life date (if shelf life dating is used) or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve sample; and - Samples consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the supplement meets product specifications. The reserve program was confirmed to be following the above noted requirements.
LS16	Analyze the firm's program for raw material reserve samples to ensure it meets requirements. NPA.E.4.1, NPA.E.4.3	Acceptable			Reserve samples are collected and held for each lot of raw materials (components) received. The auditor checked that raw material reserve samples were maintained via the following: - Held in suitable containers to protect against degradation - Retained for 1 year past shelf life date from the latest expiration date of any lots containing raw materials - Consist of at least twice the quantity necessary for all required tests and/or examinations Samples reviewed met all of the criteria.
LS17	Analyze the tests and/or examinations used to verify specifications to see if they are appropriate and scientifically valid. §111.320(a)	Unacceptable	Major	CAR-8	The auditor could not verify written documentation that established methodologies were being followed. This documentation included the results of the testing/examination. All test and examination methodologies have not been verified as appropriate for their intended use. All test and examination methods used to confirm established specifications were not scientifically valid. Procedures reviewed: 1: QAQC-4011 - Laboratory Qualification Program - 6/7/18 Test methods reviewed: 1: No internal test methods The auditor ver fied that at least one of the following tests/examinations were used to verify specifications: □ Gross organoleptic analysis □ Macroscopic analysis □ Microscopic analysis □ Chemical analysis □ Other scientifically valid methods: (describe here) Nonconformance noted: There are no internal methods or reference to use of compendial methods. The facility is conducting pH density and alcohol testing; however there is no reference method established or raw data available for review.
LS18	Ensure expiration or shelf-life dates have been set for all finished, packaged, labeled dietary supplements and the company has data to support the expiration or shelf-life of the products. NPA.E.2.1 and NPA.E 2.2	Acceptable			Expiration or shelf-life dates have been set for all finished packaged labeled dietary supplements as applicable. There is data to support expiration or shelf-life dates. The auditor reviewed the following product expiration or shelf-life studies: 1) [redacted] expiration date letter 2) Additional studies are currently in process
LS19	Check that components or products are appropriately rejected when specifications are not met, unless QC personnel has otherwise approve reprocessing. §111.77(a,b,c); 111.425; 111.113(a)	Acceptable			Where specifications were found to be nonconforming and no reprocessing or adjustment took place Quality personnel rejected the component packaging labeling or finished product as appropriate. QC reviewed records for OOS product: 1: Item MGR024 LOT 19-014 Finished packaged and labeled dietary supplements that were rejected were clearly identified held and controlled under a quarantine system for appropriate disposition.
LS20	Confirm corrective action plans have been established for when established specifications are not met. §111.75(i)	Acceptable			Corrective action plans were initiated when established specifications were not met. The auditor reviewed the following SOP(s) for corrective actions and failures: SOP 1: CMPL-5005 - Corrective Action Plan - 5/20/19 SOP 2: QAQC-4017 - Deviations - 5/20/19 Records of Corrective Actions reviewed: 1: CAPA lot 12612 10/18/18 2: CAPA lot 12498 12/21/18

	Requirement	Acceptable?	NC Type	CAR Number	Comment
	NSF/ANSI 173 - 2016				
LS21	Review the firm's process for testing for diethylene glycol (DEG) in glycerin ingredients to ensure it includes identification testing, limit testing for DEG by Gas Chromatogram, as stated in the USP monograph for Glycerin. Other suitable and validated methods may be used if verified equivalent to the USP testing requirement. NSF/ANSI 173-2016 Section 8.4 Requirements for testing of DEG in glycerin ingredients 5.3.6.2 Contaminants in glycerin	Not Applicable			ANSI/NSF 173 Not Part of Scope.
LS22	Review the firm's testing results to ensure limits for DEG are not exceeded in ingredients and final products. NSF/ANSI 173-2016 Section 8.4 Requirements for testing of DEG in glycerin ingredients 5.3.6.2 Contaminants in glycerin	Not Applicable			ANSI/NSF 173 Not Part of Scope.
LS23	The manufacturers should have controls in place to assess and prevent rancidity for products containing oils or combination of o ls. NSF/ANSI 173-2016 section 8.5 Requirements for Oils	Not Applicable			ANSI/NSF 173 Not Part of Scope.
LS24	Evaluate manufacturers procedures and specifications for testing ingredients for microbial contamination. Evaluation of ingredients includes vitamin, minerals, botanicals (non-extract), and botanicals (extract/other dietary supplement ingredients). NSF/ANSI 173-2016 section 5.3.3 Microbiological contaminants table 8.1 Requirements of limits for microbial contaminants for Dietary Ingredients	Not Applicable			ANSI/NSF 173 Not Part of Scope.
LS25	Evaluate manufacturers procedures and specifications for testing ingredients for pathogenic contamination. Evaluation of ingredients includes vitamin, minerals, botanicals (non-extract), and botanicals (extract/other dietary supplement ingredients). NSF/ANSI 173-2016 NSF/ANSI 173-2016 section 5.3.3 Microbiological contaminants table 8.2 Requirements of limits for pathogenic microbial contaminants in Dietary Ingredients	Not Applicable			ANSI/NSF 173 Not Part of Scope.
LS26	Evaluate manufacturers procedures and specifications for testing ingredients for acceptable limits of microbial contaminants. Evaluation of final products with vitamin, minerals, botanicals (non-extract), and botanicals (extract/other dietary supplement ingredients). NSF/ANSI 173-2016 section 5.3.3 Microbiological contaminants table 8.3 Requirements of limits for microbial contaminants in Finished Product Examples of Categories: 1: Product containing only Vitamin C and Zinc 2: Product containing Vitamin C, Zinc, and Green Tea Extract 3: Product containing Vitamin C, Zinc, and Echinacea	Not Applicable			ANSI/NSF 173 Not Part of Scope.

	Requirement	Acceptable?	NC Type	CAR Number	Comment
LS27	Evaluate manufacturers procedures and specifications for testing final products for acceptable limits of pathogenic contaminants. Evaluation of final products with vitamin, minerals, botanicals (non-extract), and botanicals (extract/other dietary supplement ingredients). NSF/ANSI 173-2016 section 5.3.3 Microbiological contaminants table 8.4 Requirements of limits for pathogenic contaminants in Finished Product Examples of Categories: 1: Product containing only Vitamin C and Zinc 2: Product containing Vitamin C, Zinc, and Green Tea Extract 3: Product containing Vitamin C, Zinc, and Echinacea	Not Applicable			ANSI/NSF 173 Not Part of Scope.
LS28	Evaluate manufacturers procedures and specifications for testing final products for acceptable limits of aristolochic acid contaminant in botanicals. NSF/ANSI 173-2016 Section 5.3.4 Aristolochic Acid Annex A, Table A 1 7.4 Test methods for chemical contaminants Examples of botanicals requiring testing for aristolochic acid: 1. Aristolochia acuminata and any Aristolochia species 2. Asarun canadense and any Asarum species 3. Cocculus carolinus and any Cocculus species 4. Stephania tetrandra and any Staphania species	Not Applicable			ANSI/NSF 173 Not Part of Scope.

Score Matrix

	System	Risk Priority Number	Possible Number of Points	Points Earned
QS	Quality System	100	14.63	14.63
FE	Facilities and Equipment System	94	26.83	25.20
MS	Material System	100	17.07	17.07
PS	Production System	75	13.01	9.76
PA	Packaging System	67	4.88	3.25
LS	Laboratory System	62	23.58	14.63
	Final Risk Priority Number	85	100	84.55284553
Based on Major or Critical NC, a Follow-up is Recommended.				



RPN	Risk Level
100 to 96	Reasonable Risk
95.99 - 89.99	Limited Risk
89.98 - 80.99	Average Risk
80.98 to 71.99	Medium Risk
71.98 and below	High Risk