UL Registrar LLC

Retail Factory Audit Report
Supplements 21 CFR Part 111 et al
21 CFR Part 11 (When Applicable)

QT Report: 128417	Audit Dates: 8/5 - 8/7/2014	Report Date: 8/8/2014
Vendor Name: **Garmon Corporation**	*Factory Name:* **Garmon Corporation**	*Lead Auditor:* **Greg Berry**
Audit Activity: **Surveillance #1**	*Address:* **27461 Via Industria Temecula, CA 92590 Warehouse - Finished Goods**	*Auditor(s):* **N/A**

Fail	Pass With Conditions	Pass
		X
Noncompliant	Marginal	Compliant

Factory Grade: Compliant

Factory Score: 82.88%

#Major CAPAs: 1

#Minor CAPAs: 3

CAPA follow-up required? Yes

All program requirements for certificate met?
(RCP Cert Committee only)

NO	YES	NOT RCP
X		

Scope of audit:	*Products:*
This is an annual surveillance audit of a multi-site manufacturer & packager of dog & cat dietary supplements.	***Dog & cat dietary supplements: tablets, liquids, soft chew (joint support, ear wax remover, tear stain topical / ingestible vitamins, skin & coat).***

Most recent audit date:	*What entity performed the audit?*	*Audit result:*
8/28/2013	**NASC**	**Certification**

Types of certifications maintained:	*FDA Registration Type and Number:*
UL R - RCP Dietary Supplement NASC - Pet Food	**ID / FEI Bioterrorism - 011706236 FEI - 3003068085**

Company Representative during audit:
Judith Contreras - QA / QC Manager

Production Area- Ft ^{2} :	*# Production lines:*	*Packaging Area- Ft ^{2} :*	*# Packaging lines:*
1. N/A 2. 6,500 3. 2,300 4. 2,000	1. N/A 2. Blenders - 2, Portable Blender - 2, Hammer Mill - 1, Press - 6 3. Kettles - 4 4. Blender - 2, Extruder - 1	1. N/A 2. Included in production 3. Included in production 4. Included in production	1. N/A 2. Powder 1, Pouch 1 3. Filler - 4 4. Bag, Pouch & Cup 1

Warehouse - Ft ^{2} :	*Total Plant Size- Ft ^{2} :*
1. 12,548 2. 5,000 3. 7,300 4. 5,300	1. 12,548 2. 11,080 3. 9,664 4. 7,300

Additional Sites Under Audit:

2. 27497 Via Industria, Temecula, CA 92590 - Manufacturing and Packaging - Powders
3. 27503 Via Industria, Temecula, CA 92590 - Manufacturing and Packaging - Liquids
4. 42389 Winchester, Temecula, CA 92590 - Manufacturing and Packaging - Extrusion

COMPLETE SECTION BELOW FOR CAPA FOLLOW-UP ONLY

QT Report: 157667	Audit Dates: 12/1/2014	Report Date: 12/3/2014

Fail	Pass With Conditions	Pass
		X
Noncompliant	Marginal	Compliant

Factory Grade: Compliant

Factory Score: 89.18%

#Major CAPAs: 0

#Minor CAPAs: 3

Re-Audit required? No

All program requirements for certificate met?
(RCP Cert Committee only)

NO	YES	NOT RCP
	X	

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
	Quality System												
	Subpart B – Personnel												
QS1	**Does the factory exclude people from your operation who might be a source of microbial contamination due to illness, etc.?** *Must be documented in SOP or other format to score YES. 111.10(a)(1)*	2	2	Y	0		The restriction of personnel who are ill from the production areas are documented in the disease control procedure. The document includes instruction on incidents of disease and the reporting on the disease control / cleanliness report.	2	2	Y	0		The restriction of personnel who are ill from the production areas is documented in the disease control procedure. The document includes instruction on incidents of disease and the reporting on the disease control / cleanliness report.
QS2	**Have employees been instructed to notify their supervisors if they have health conditions that might lead to contamination of any material?** *111.10(a)(2)*	2	2	Y	0		The communication of illness is performed and documented on disease control / cleanliness reports.	2	2	Y	0		The communication of illness is performed and documented on disease control / cleanliness reports.
QS3	**Are hygienic practices used to protect against contamination of material or contact surfaces?** *111,10(b)*	2	2	Y	0		Employees are trained in hygienic practices that are used to help protect materials and contact surfaces against potential contamination. Staff were observed adequately implementing good hygiene.	2	2	Y	0		Employees are trained in hygienic practices that are used to help protect materials and contact surfaces against potential contamination. Staff were observed adequately implementing good hygiene.
QS4	**Does the factory require the wearing of outer garments and employees maintain adequate personal hygiene?** *111.10(b)(1)(2)*	2	2	Y	0		Factory gowning requirements include the use of company supplied lab coats or uniforms, hair nets and beard covers. Gloves are worn by employees involved in direct product handling. Staff were observed adhering to the policy.	2	2	Y	0		Factory gowning requirements include the use of company supplied lab coats or uniforms, hair nets and beard covers. Gloves are worn by employees involved in direct product handling. Staff were observed adhering to the policy.
QS5	**Do the employees wash hands thoroughly in an adequate hand washing facility?** *111.10(b)(3)(i)(ii)*	2	2	Y	0		The facility has an adequate number of employee hand washing stations throughout the facility. Employees were observed utilizing the stations and practicing good hygiene.	2	2	Y	0		The facility has an adequate number of employee hand washing stations throughout the facility. Employees were observed utilizing the stations and practicing good hygiene.
QS6	**Are employees required to remove jewelry when in the production area?** *111.10(b)(4)*	2	2	Y	0		Jewelry restrictions in production areas are included in the dress code for production and warehouse procedure and the production controls - personal cleanliness procedures. Staff were observed adhering to the policy.	2	2	Y	0		Jewelry restrictions in production areas are included in the dress code for production and warehouse procedure and the production controls - personal cleanliness procedures. Staff were observed adhering to the policy.
QS7	**Are gloves used in handling material?** *111.10(b)(5)*	3	3	Y	0		Employees in direct contact with product were observed wearing gloves.	3	3	Y	0		Employees in direct contact with product were observed wearing gloves.
QS8	**Were appropriate, are hair nets, beard covers, etc. worn?** *111.10(b)(6)*	3	3	Y	0		Staff were observed wearing hair nets, beard covers and lab coats or uniforms while involved in production operations.	3	3	Y	0		Staff were observed wearing hair nets, beard covers and lab coats or uniforms while involved in production operations.
QS9	**Are personal clothing/belongings stored remote to operations?** *111.10(b)(7)*	2	2	Y	0		The producer has provided dedicated lockers outside of production areas for staff to temporarily store personal clothing and belongings while working.	2	2	Y	0		The producer has provided dedicated lockers outside of production areas for staff to temporarily store personal clothing and belongings while working.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
QS10	**Does the factory restrict eating, drinking, etc. from operations area?** *111.10(b)(8)*	2	2	Y	0		Eating, drinking and smoking are restricted from production areas. The facility has a dedicated lunch room for employee eating and drinking. Visitors and contractors are notified of the requirement prior to entry in the facility. Staff were observed adhering to the policy during the audit.	2	2	Y	0		Eating, drinking and smoking are prohibited in production areas. The facility has a dedicated lunch room for employee eating and drinking. Visitors and contractors are notified of the requirement prior to entry in the facility. Staff were observed adhering to the policy during the audit.
QS11	**Are there qualified employees with proper training, experience and education?** *111.12(a)(c)*	3	3	Y	0		The producer has an established training program with a training manager and records of training activities. Training records include job description, employee testing matrix, proficiency testing and certificates of training. Based on observation and review of selected training records for manufacturing and QC staff, employees are adequately trained to perform assigned duties.	3	3	Y	0		The producer has an established training program with a training manager and records of training activities. Training records include job description, employee testing matrix, proficiency testing and certificates of training. Based on observation and review of selected training records for manufacturing and QC staff, employees are adequately trained to perform assigned duties.
QS12	**Has the factory identified who is responsible for the quality control operation?** *111.12(b)*	3	3	Y	0		The producer has a Quality Manager responsible for the oversight of facility Quality programs.	3	3	Y	0		The producer has a Quality Manager responsible for the oversight of facility Quality programs.
	Subpart C – Physical Plant and Grounds **Subpart I – Production and Process Control System: Requirements for the Batch Production Record**												
QS13	**Does the batch records contain all the information in the master manufacturing record (7.1), including identity of equipment/lines, cleaning records, labels, results of tests and final disposition of product?** *111.260*	3	3	Y	0		Based on selected batch records reviewed, the batch records are an accurate reflection of the master manufacturing record (MMR). The records were found to include a formulation sheet, batch size, lot number, blend instructions, Quality control in-process check sheet, labels, final batch summary sheet, packaging check off sheet, formulation analysis and the QC analytical & inspection report.	3	3	Y	0		Based on selected batch records reviewed, records are an accurate reflection of the master manufacturing record (MMR). The records were found to include a formulation sheet, batch size, lot number, blend instructions, Quality control in-process check sheet, labels, final batch summary sheet, packaging check off sheet, formulation analysis and the QC analytical & inspection report.
	Subpart N – Returned Dietary Supplements												
QS14	**Are returned dietary supplements quarantined and does quality control personnel conduct a material review on product disposition?** *Implementation Guidance*	3	3	Y	0		The producer has a documented product return procedure, with a complaint and product return form, for the receipt of product. Procedurally, the QC department is required to evaluate product and determine if it is to be destroyed or re-stocked into inventory. There were no records of returns to review for compliance since the last audit.	3	3	Y	0		The producer has a documented product return procedure, utilizing a complaint and product return form, for the receipt of product. Procedurally, the QC department is required to evaluate product and determine if it is to be destroyed or re-stocked into inventory. There were no records of returns to review for compliance since the last audit.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
	Subpart O – Product Complaints												
QS15	**Does a qualified person review all product complaints to determine possible failure to meet specifications and does quality control personnel review/approve investigations and follow up action?** *Are relevant batches and records reviewed? 111.560*	3	3	Y	0		The producer has a documented complaint and adverse event procedure describing the management of written and oral complaints. The procedure references a triage checklist, a standardized form, complainant contact information, communication with customer, QA approval and timeframe for closure. QC or compliance personnel are assigned review responsibility for complaints. Complaints are recorded on a log that includes the date, classification, product, lot number, problem, representative, QC notified and QC investigation notes. Adverse events are recorded on the NASC adverse event form. Selected complaints and adverse events were reviewed and found to be adequately reported.	3	3	Y	0		The producer has a documented complaint and adverse event procedure describing the management of written and oral complaints. The procedure references a triage checklist, a standardized form, complainant contact information, communication with customer, QA approval and timeframe for closure. QC or compliance personnel are assigned review responsibility for complaints.
QS16	**Does the complaint record contain the investigation, product lot number, complainant information and reply to the complainant?** *111.570*	2	2	Y	0		The producer has a documented complaint and adverse event procedure describing the management of written and oral complaints. The procedure references a triage checklist, a standardized form, complainant contact information, communication with customer, QA approval and timeframe for closure. QC or compliance personnel are assigned review responsibility for complaints. Complaints are recorded on a log that includes the date, classification, product, lot number, problem, representative, QC notified and QC investigation notes. Adverse events are recorded on the NASC adverse event form. Selected complaints and adverse events were reviewed and found to be adequately reported.	2	2	Y	0		Complaints are recorded on a log that includes the date, classification, product, lot number, problem, representative, QC notified and QC investigation notes. Adverse events are recorded on the NASC adverse event form. Selected complaints and adverse events were reviewed and found to be adequately reported.
	Subpart P – Records and Recordkeeping												
QS17	**Are written records kept for one year past expiry date or two years beyond the date of distribution of the last batch associated with those records?** *111.605*	2	2	Y	0		The production records are retained for a minimum of one year past the product expiration or best buy date.	2	2	Y	0		The production records are retained for a minimum of one year past the product expiration or best buy date.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
	Traceability												
QS18	**Has the vendor factory established effective procedure(s) to locate product at any given state of production including pre-production, in-process production and post production?** *Implementation Guidance*	3	3	Y	0		Material and product identification and trace is effectively performed through the assignment of material item codes, and lot numbers to incoming materials and finished product. The lot numbers were found to be affixed to material containers stored in the facility and where applicable, documented in production records. Observations and review of batch records helped verify material traceability. The producer has a product recall procedure and performs an annual mock recall to test effectiveness. The last mock recall was successfully performed on 04/14/14, utilizing recall info link to perform the recall.	3	3	Y	0		Material and product identification and trace is effectively performed through the assignment of material item codes, and lot numbers to incoming materials and finished product. The lot numbers were found to be affixed to material containers stored in the facility and where applicable, documented in production records. The producer has a product recall procedure and performs an annual mock recall to test procedure effectiveness. The last mock recall was successfully performed on 04/14/14, utilizing Recall Info Link to perform the recall.
QS19	**Can the factory demonstrate forward traceability by random selection of shipped finished product?** (*The vendor must provide number of cases produced on randomly selected date and identify where those cases were shipped. If full reconciliation cannot be provided, answer No .*) *Implementation Guidance*	3	3	Y	0		The producer was able to successfully trace requested finished packaged product from the warehouse to the point of destination. The records used to perform material trace included the Data Pro inventory transaction history report that includes the material, lot number, purchase order and customer or vendor.	3	3	Y	0		The producer was able to successfully trace requested finished packaged product from the warehouse to the point of destination. The records used to perform material trace included the Data Pro inventory transaction history report that includes the material, lot number, purchase order and customer or vendor.
QS20	**Can the factory demonstrate backward traceability by random selection of finished product code?** (*The vendor must provide evidence of all ingredient lot codes (and amounts) included in selected finished product and the supplier of each ingredient or component. If full reconciliation cannot be provided, answer No.*) *Implementation Guidance*	3	3	Y	0		The producer was able to successfully trace requested materials and components that were included in the production records. The trace originated from the batch record to initial material receipt into the facility. Documents used for material trace include the batch record raw material & finished goods quarantine release form, COA and the incoming receiving log.	3	3	Y	0		The producer was able to successfully trace requested materials and components that were included in the production records. The trace originated from the batch record to initial material receipt into the facility. Documents used for material trace include the batch record raw material & finished goods quarantine release form, COA and the incoming receiving log.
	Facilities and Equipment												
	Subpart C – Physical Plant and Grounds												
FE1	**Is the physical plant grounds free of litter/waste, with adequate drainage and vegetation cut within immediate vicinity of plant?** *111.15(a)(1,2,3,4)* *Implementation Guidance*	2	2	Y	0		The production facility exterior was found to be clean and in good repair with adequate drainage and landscaping.	2	2	Y	0		The production facility exterior was found to be clean and in good repair with adequate drainage and well maintained landscaping.
FE2	**Is the physical plant clean and in repair to prevent contamination of material on contact surfaces?** *111.15(b)(1,2)* *Implementation Guidance*	2	2	Y	0		The facility was found to be clean, orderly and in good repair helping to prevent contamination of material contact surfaces.	2	2	Y	0		The facility was found to be clean, orderly and in good repair helping to prevent contamination of material contact surfaces.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
FE3	**Is there a list of approved chemicals for maintaining the sanitation of the facility?** *Review approved chemical list. Cross check with chemicals in storage area. Also randomly select 3 chemicals and ensure MSDS can be provided.* *Implementation Guidance*	1	1	Y	0		A list of approved chemicals for maintaining the sanitation of the facility was provided for review. MSDS for the chemicals are conveniently available to staff. The chemicals storage area was adequate and designed to prevent contamination.	1	1	Y	0		A list of approved chemicals for maintaining the sanitation of the facility was provided for review. MSDS for the chemicals are conveniently available to staff. The chemicals storage area was adequate and designed to prevent contamination.
FE4	**Are cleaning and sanitizing agents appropriate for use, are they approved for food grade use and are they stored to prevent contamination?**	3	3	Y	0		Oxonia and IPA are used as sanitization agents. The cleaning agents include Shine, Flex cb-9, Odokleen. Labels were provided for materials. Review of the labels found, process equipment cleaning materials approved for use in food manufacturing facilities.	3	3	Y	0		Oxonia and IPA are used as sanitization agents. The cleaning agents include Shine, Flex cb-9, Odokleen. Labels were provided for materials. Review of the labels found, process equipment cleaning materials approved for use in food manufacturing facilities.
FE5	**Are effective measures being taken to exclude pests from the physical plant and to protect against contamination of materials?** *111.15(d)(1,2,3)*	3	3	Y	0		The producer has a documented pest control procedure and has subcontracted the management to a local commercial pest control service provider (PCO). The PCO visits the facility once per month. Control is performed using bait stations and interior tin traps. The facility was observed to be void of any obvious pest activity in production or support areas.	3	3	Y	0		The producer has a documented pest control procedure and has subcontracted the management to a local commercial pest control service provider (PCO). The PCO visits the facility once per month. Control is performed using bait stations and interior tin traps. The facility was observed to be void of any obvious pest activity in production or support areas.
FE6	**Is the water safe and sanitary at suitable temperatures for use where water does not become a component of the dietary supplement?** *Water testing must be conducted that includes acceptable limits of potable water, less than 500 cfu and 100 cfu and 100 cfu for purified water. 111.15(e)(1)*	3	0	N	0	Minor	**Minor ca-001-2014-gar issued in FE6, included in MS1.** Water testing out of specification events are not adequately documented and investigated. The producer utilizes both city potable and in-house generated deionized water for facility supply and manufacturing processes. Weekly & monthly micro - HPC, E.coli & total coliform testing is performed on both the incoming potable and the purified water supplies. The documented specifications = HPC <100 mpn, E.coli < 1 ml and total coliform < 1 ml. Recent testing results were reviewed during the audit for each production site and found to be generally conforming to specifications. However, at the Winchester facility it was observed that the 05/19/14 HPC results exceeded specification at > 738 mpn, the producer indicated that the system was taken off-line after results were obtained, however there has not been a documented investigation or subsequent follow-up addressing the cause, corrective action or potential product impact. Regarding classification of the observation, it was noted that the water is just used for equipment cleaning that is subject to sanitization and finished products are tested for micro as part of release.	3	0	N	0	Minor	**Minor ca-001-2014-gar issued in FE6, included in MS1 (This CAPA remains OPEN, to be verified at the next regularly scheduled audit).** Water testing out of specification events are not adequately documented and investigated. The producer utilizes both city potable and in-house generated deionized water for facility supply and manufacturing processes. Weekly & monthly micro - HPC, E.coli & total coliform testing is performed on both the incoming potable and the purified water supplies. The documented specifications = HPC <100 mpn, E.coli < 1 ml and total coliform < 1 ml. Recent testing results were reviewed during the audit for each production site and found to be generally conforming to specifications. However, at the Winchester facility it was observed that the 05/19/14 HPC results exceeded specification at > 738 mpn, the producer indicated that the system was taken off-line after results were obtained, however there has not been a documented investigation or subsequent follow-up addressing the cause, corrective action or potential product impact. Regarding classification of the observation, it was noted that the water is just used for equipment cleaning that is subject to sanitization and finished products are tested for micro as part of release.
FE7	**Is the plumbing and convey of sewage adequate and would not contaminate material?** *This must include a drain sanitization program to score YES. 111.15(f)(1,2,3,4,5)*	2	2	Y	0		The plumbing for water and sewage waste is adequately designed to route waste away from production areas.	2	2	Y	0		The plumbing for water and sewage waste is designed to adequately route waste away from production areas.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
FE8	**Are bathrooms and hand-washing facilities clean and not a source of contamination with suitable water temperature and single use towels and/or dryers?** *111.15(i)*	2	2	Y	0		The employee restrooms and the hand wash station located in the facility are clean and well supplied with potable water, disposable towels and soap to help aide in employee hygiene.	2	2	Y	0		The employee restrooms and the hand wash station located in the facility are clean and well supplied with potable water, disposable towels and soap to help aide in employee hygiene.
FE9	**Is trash disposal suitable to prevent pests and contamination of material?** *111.15(j)(1,2,3,4)*	2	2	Y	0		Facility and production waste are appropriately consolidated in identified containers and removed from the production areas. The waste is disposed of outside of the facility in a covered dumpster which is emptied and transported off-site by a local waste collection company.	2	2	Y	0		Facility and production waste are appropriately consolidated in identified containers and removed from the production areas. The waste is disposed of outside of the facility in a covered dumpster which is emptied and transported off-site by a local waste collection company.
FE10	**Is there a sanitation supervisor?** *111.15(k)*	2	2	Y	0		The facility has a designated sanitation supervisor with documented food safety and sanitation for food manufacturer training.	2	2	Y	0		The facility has a designated sanitation supervisor with documented food safety and sanitation for food manufacturer training.
FE11	**Is the physical plant of suitable size and construction to facilitate maintenance and cleaning?** *111.20(a)*	2	2	Y	0		The facility was observed to be adequate in size providing sufficient space for all manufacturing, storage, cleaning and maintenance activities.	2	2	Y	0		The facility was observed to be adequate in size providing sufficient space for all manufacturing, storage, cleaning and maintenance activities.
FE12	**Is there adequate space for orderly placement of equipment and holding of material as is necessary for cleaning and maintenance to prevent contamination?** *Ensure that there is adequate barriers or line separation between manufacturing and packaging lines to ensure no co-mingling can occur to Score YES. 111.20(b)*	3	3	Y	0		The warehouse and the production facility spaces are designed and organized to provide for logical flow with established segregation of components and products to help prevent material commingling or contamination. The flow also helps aide in effective cleaning and maintenance activities.	3	3	Y	0		The warehouse and the production facility spaces are designed and organized to provide for logical flow with established segregation of components and products to help prevent material commingling or contamination. The flow also helps aide in effective cleaning and maintenance activities.
FE13	**Are proper precautions being taken to prevent mix ups or contamination of material by having separate or defined areas for activities?** *111.20(c)(1,2,3,4,5,6,7)*	3	3	Y	0		The facility has dedicated areas for warehousing shipping and receiving, blending, tableting, extrusion, filling and packaging steps. The areas are separated by permanent walls, doors and hanging plastic curtains. Contamination or comingling issues were not observed.	3	3	Y	0		The facility has dedicated areas for warehousing shipping and receiving, blending, tableting, extrusion, filling and packaging steps. The areas are separated by permanent walls, doors and hanging plastic curtains. Contamination or comingling issues were not observed.
FE14	**Are floors, walls and ceilings in adequate condition, cleaned and in good repair?** *111.20(d)(1)(i)*	2	2	Y	0		The production and warehouse facilities are structurally sound with effectively closing doors and windows that are sealed and interior walls and ceilings that are generally in good condition.	2	2	Y	0		The production and warehouse facilities are structurally sound with effectively closing doors and windows that are sealed and interior walls and ceilings that are generally in good condition.
FE15	**Are fixtures, pipes and ducts constructed to prevent contamination of materials?** *111.20(d)(1)(ii)*	2	2	Y	0		The facility is designed with overhead pipe and fixtures, the installations were generally observed to be adequate in helping to prevent the potential for overhead contamination of product.	2	2	Y	0		The facility is designed with overhead pipe and fixtures, the installations were generally observed to be adequate in helping to prevent the potential for overhead contamination of product.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
FE16	**Is there adequate ventilation or environmental controls to prevent contamination of material?** *111.20(d)(1)(iii)*	2	2	Y	0		The facility has in-house dust collection and incoming air that is filtered through the HVAC system.	2	2	Y	0		The facility has in-house dust collection and incoming air that is filtered through the HVAC system.
FE17	**Is the control of temperature and humidity maintained to ensure dietary supplement quality?** *111.20(d)(1)(iv)*	2	2	Y	0		The products under review do not have specified storage requirements. The facility warehousing is structurally sound and designed to protect product from extreme environmental conditions.	2	2	Y	0		The products under review do not have specified storage requirements. The facility warehousing is structurally sound and designed to protect product from extreme environmental conditions.
FE18	**If air-blowing equipment is used, is it operated to prevent microorganisms and particulate matter contamination to material and contact surfaces?** *111.20(d)(2)*	3	0	N/A	3		Air blowing equipment with potential product impact is not utilized in processing operations.	3	0	N/A	3		Air blowing equipment with potential product impact is not utilized in processing operations.
FE19	**Is the lighting adequate in the physical plant and in areas where materials are examined or processed, are lights protected to prevent contamination?** *111.20(e)(1,2,3)(f)(g)(1,2,3,4)*	2	2	Y	0		The building has adequate, protected overhead lighting throughout the warehouse, shipping & receiving, blending, filling, tablet compression, filling & packaging and lab areas. There were no signs of obvious overhead light damage or breakage.	2	2	Y	0		The building has adequate, protected overhead lighting throughout the warehouse, shipping & receiving, blending, filling, tablet compression, filling & packaging and lab areas. There were no signs of obvious overhead light damage or breakage.
FE20	**Does the factory make and keep records of the written procedures for cleaning the physical plant and pest control?** *111.23(a)(b)*	2	2	Y	0		Cleaning records were found to be complete, current and include operator and verifier for completion of each activity. Records reviewed were found to be complete. The pest control records, pest control service provider (PCO) documentation was found to be current and complete.	2	2	Y	0		Cleaning records were found to be complete, current and include operator and verifier for completion of each activity. Records reviewed were found to be complete. The pest control records, pest control service provider (PCO) documentation was found to be current and complete.
	Subpart D – Equipment and Utensils												
FE21	**Are there written procedures for maintenance and calibration of instruments and controls?** *111.25(a)(b)*	3	3	Y	0		The producer utilizes instrumentation throughout processing and facilities to include flow meters, thermometers, scales, metal detectors, check weighers and analytical instrumentation. There are documented procedures for the calibration of instrumentation. A matrix schedule with instrumentation and current certificates of calibration for selected equipment, such as flow meters and check weighers was provided for review.	3	3	Y	0		The producer utilizes instrumentation throughout processing and facilities to include flow meters, thermometers, scales, metal detectors, check weighers and analytical instrumentation. There are documented procedures for the calibration of instrumentation. A matrix schedule with instrumentation and current certificates of calibration for selected equipment, such as flow meters and check weighers was provided for review.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
FE22	**Are there written procedures for cleaning and sanitizing equipment, utensils and contact surfaces used in manufacturing or holding material?** *111.25(c)*	3	0	N	0	Minor	**Minor ca-003-2014-gar issued in FE22.** Cleaning procedures are not adequately defined. The producer has equipment specific procedures for cleaning and preparation. Cleaners and sanitizers are prepped by the QC department and recorded on a log as evidence of solution preparation. The procedures reference the use of general sanitation agents which are identified on the approved chemical list, however, the documents do not specifically identify which cleaner, where to use and the concentrations. In addition, the procedure references the use of alcohol for sanitizing, but does not describe the concentration to use, whether 70 or 100%.	3	0	N	0	Minor	**Minor ca-003-2014-gar issued in FE22 (This CAPA remains OPEN, to be verified at the next regularly scheduled audit).** Cleaning procedures are not adequately defined. The producer has equipment specific procedures for cleaning and preparation. Cleaners and sanitizers are prepped by the QC department and recorded on a log as evidence of solution preparation. The procedures reference the use of general sanitation agents which are identified on the approved chemical list, however, the documents do not specifically identify which cleaner, where to use and the concentrations. In addition, the procedure references the use of alcohol for sanitizing, but does not describe the concentration to use, whether 70 or 100%.
FE23	**Is equipment (including utensils) used in manufacturing appropriate in design and will not contaminate material?** *111.27(a)(1,2,3,4)*	3	3	Y	0		Production equipment with product contact surfaces are composed of cleanable stainless steel and synthetic surfaces. Each is designed to help prevent contamination of any materials during the production process.	3	3	Y	0		Production equipment with product contact surfaces is composed of cleanable stainless steel and synthetic surfaces. Each is designed to help prevent contamination of any materials during the production process.
FE24	**If cold storage units are used, are they fitted with a temperature measuring device and have an automated device for regulating temperature or an alarm system?** *111.27(a)(5)(i,ii)*	2	2	Y	0		The refrigerator used for storage of materials was found to be monitored with a calibrated thermometer. The refrigerator is monitored daily for temperature.	2	2	Y	0		The refrigerator used for storage of materials was found to be monitored with a calibrated thermometer. The refrigerator temperature is reviewed and recorded daily.
FE25	**Are instruments or controls used in manufacturing accurate, precise, well maintained, calibrated and adequate in number?** *111.27(a)(6)(i,ii,iii)*	2	2	Y	0		The producer utilizes instrumentation throughout processing and facilities to include flow meters, thermometers, scales, metal detectors, check weighers and analytical instrumentation. There are documented procedures for the calibration of instrumentation. A matrix schedule with instrumentation and current certificates of calibration for selected equipment such as flow meters and check weighers were provided for review. Review of records found instrumentation to be considered accurate.	2	2	Y	0		The producer utilizes instrumentation throughout processing and facilities to include flow meters, thermometers, scales, metal detectors, check weighers and analytical instrumentation. There are documented procedures for the calibration of instrumentation. A matrix schedule with instrumentation and current certificates of calibration for selected equipment such as flow meters and check weighers were provided for review. Review of records found instrumentation to be considered accurate.
FE26	**Is compressed air (or other gases) used in manufacturing treated to prevent contamination?** *Determine if the compressed air system is being used in product contact areas and equipment. If so, ensure it is being treated properly to prevent contamination from micro, moisture and particulates. 111.27(a)(7)*	3	0	N/A	3		Compressed air with potential product impact is not utilized in processing operations.	3	0	N/A	3		Compressed air with potential product impact is not utilized in processing operations.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
FE27	**Is necessary equipment, utensils and contact surfaces used in manufacturing clean and sanitized?** *111.27(b)(3)(d)*	3	3	Y	0		Equipment and utensils are subject to cleaning & sanitization prior to use in production. Processing equipment was observed to be adequately cleaned.	3	3	Y	0		Equipment and utensils are subject to cleaning & sanitization prior to use in production. Processing equipment was observed to be adequately cleaned.
FE28	**If Allergens are run in the facility, is there an Allergen program that provides adequate data that Allergens are removed in the cleaning process?** *Implementation Guidance*	3	0	N/A	3		The producer does not handle any of the eight major allergens in this facility.	3	0	N/A	3		The producer does not handle any of the eight major allergens in this facility.
FE29	**Are single service articles such as utensils stored, handled, used and disposed of appropriately?** *Ensure that raw materials are also sampled prior to release with single-service sanitary utensils to score YES. 111.27(b)(5)(i,ii)*	3	3	Y	0		Single service disposable utensils used in the material sampling process are discarded after each use.	3	3	Y	0		Single service disposable utensils used in the material sampling process are discarded after each use.
FE30	**Is equipment (automated, mechanical, electrical) capable of operating within the operating limits required by the process?** *111.30(a)(b)(c)(d)(e)*	3	3	Y	0		Equipment used in the facility for the blending, compression, extrusion, filling and packaging activities was observed to be adequately designed and sized to manufacture the products under review.	3	3	Y	0		Equipment used in the facility for the blending, compression, extrusion, filling and packaging activities was observed to be adequately designed and sized to manufacture the products under review.
FE31	**Are there procedures for individual records for cleaning and sanitizing equipment?** *111.35(2)*	3	3	Y	0		The producer provided current records of equipment and area cleaning records. Selected records reviewed included the powder / tabs daily cleaning procedures log: weekly record 2 x / day cleaning schedule which includes sweeping, table, room, cleaning agents, exterior dumpster clear, bottles labeled. Records were found to be current and complete.	3	3	Y	0		The producer provided current records of equipment and area cleaning records. Selected records reviewed included the powder / tabs daily cleaning procedures log: weekly record 2 x / day cleaning schedule which includes sweeping, table, room, cleaning agents, exterior dumpster clear, bottles labeled. Records were found to be current and complete.
FE32	**Does documentation on calibration of equipment include a reference standard, method, date and person who performed the work?** *111.35(3)(4)*	2	2	Y	0		Selected calibration records reviewed found the calibration documentation to include reference standards, methods, date and the technician performing the calibration.	2	2	Y	0		Selected calibration records reviewed found the calibration documentation to include reference standards, methods, date and the technician performing the calibration.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
	Material & Supplier Management												
	Subpart C – Physical Plant and Grounds												
MS1	**If water is used in manufacturing does it comply with applicable Federal and State requirements?** *111.15(e)(2)*	3	0	N	0		**Minor ca-001-2014-gar issued in FE6, included in MS1.** Water testing out of specification events are not adequately documented and investigated. The producer utilizes both city potable and in-house generated deionized water for facility supply and manufacturing processes. Weekly & monthly micro - HPC, E.coli & total coliform testing is performed on both the incoming potable and the purified water supplies. The documented specifications = HPC <100 mpn, E.coli < 1 ml and total coliform < 1 ml. Recent testing results were reviewed during the audit for each production site and found to be generally conforming to specifications. However, at the Winchester facility it was observed that the 05/19/14 HPC results exceeded specification at > 738 mpn, the producer indicated that the system was taken off-line after results were obtained, however there has not been a documented investigation or subsequent follow up addressing the cause, corrective action or potential product impact. Regarding classification of the observation, it was noted that the water is just used for equipment cleaning that is subject to sanitization and finished products are tested for micro as part of release.	3	0	N	0		**Minor ca-001-2014-gar issued in FE6, included in MS1 (This CAPA remains OPEN, to be verified at the next regularly scheduled audit).** Water testing out of specification events are not adequately documented and investigated. The producer utilizes both city potable and in-house generated deionized water for facility supply and manufacturing processes. Weekly & monthly micro - HPC, E.coli & total coliform testing is performed on both the incoming potable and the purified water supplies. The documented specifications = HPC <100 mpn, E.coli < 1 ml and total coliform < 1 ml. Recent testing results were reviewed during the audit for each production site and found to be generally conforming to specifications. However, at the Winchester facility it was observed that the 05/19/14 HPC results exceeded specification at > 738 mpn, the producer indicated that the system was taken off-line after results were obtained, however there has not been a documented investigation or subsequent follow up addressing the cause, corrective action or potential product impact. Regarding classification of the observation, it was noted that the water is just used for equipment cleaning that is subject to sanitization and finished products are tested for micro as part of release.
MS2	**Does the factory make and keep records of water used as a component that meets the requirements of 111.23?** *Adequate water testing must be conducted that includes an acceptable limit of potable water less than 500 cfu and 100 cfu and 100 cfu for purified water in order to score Yes.* *Implementation Guidance*	3	3	Y	0		The DI water used in the product batching operations is recorded in the formulation section of the batch record.	3	3	Y	0		The DI water used in the product batching operations is recorded in the Formulation section of the batch record.
	Subpart M – Holding and Distribution												
MS3	**Are dietary supplements and components held under conditions so as not to affect their quality and will not lead to mix-up or contamination?** *111.455*	3	3	Y	0		Materials, ingredients and components are uniquely labeled, organized and stored in the warehouse. The warehouse is structurally sound providing adequate protection for materials from extreme environmental conditions.	3	3	Y	0		Materials, ingredients and components are uniquely labeled, organized and stored in the warehouse. The warehouse is structurally sound providing adequate protection for materials from extreme environmental conditions.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
MS4	**Is the factory holding product samples in their original container to protect against contamination and deterioration and for the required retain period?** *111.465*	3	3	Y	0		Samples are adequately stored for at least one year past the product expiration, in a dedicated area, in the laboratory.	3	3	Y	0		Samples are adequately stored for at least one year past the product expiration, in a dedicated area in the laboratory.
MS5	**Is the factory holding and distributing products under conditioning to prevent contamination and deterioration? Ensure warehouse area is secure and controlled.** *111.470*	3	3	Y	0		All final packaged products are packaged in sealed and taped shipper cases that are palletized, shrink wrapped and moved to the warehouse for temporary storage. The facility is monitored, secure and access controlled with punch code access, interior cameras and building alarms - 24 hours.	3	3	Y	0		All final packaged products are packaged in sealed and taped shipper cases that are palletized, shrink wrapped and moved to the warehouse for temporary storage. The facility is monitored, secure and access controlled with punch code access, interior cameras and building alarms - 24 hours.
	Subpart E – Requirements to Establish Production and Process Control Systems												
MS6	**Does the factory have a documented process to ensure that incoming raw materials, components, and/or sub-assemblies conform to specifications, quality standards and US Safety requirements?** *Verify that there is a process documented to ensure all incoming raw materials, components and/or sub-assemblies conform to specifications and US Safety requirements. Paint tested for lead content, etc.* *Implementation Guidance*	3	0	N	0	Minor	**Minor ca-004-2014-gar issued in MS6.** Standards used for the evaluation of incoming raw materials are not adequately maintained. The raw materials and finished goods from outside source receiving procedures describes the methods for receipt and sampling of raw material. The document references the receipt and sampling of raw material and secondary reference standards. The QA evaluation and release is recorded on the raw materials & finished goods quarantine release form - shipment damage. The form includes logged and evaluation criteria such as appearance texture, smell, taste, identification testing and release from quarantine. Review of reference standards in the incoming material receiving area found that there were several standards that had receipt dates of 2010. Review of associated COA for the materials found that one sample had passed the expiration date by 2 years and was still being used for material evaluation.	3	0	N	0	Minor	**Minor ca-004-2014-gar issued in MS6 (This CAPA remains OPEN, to be verified at the next regularly scheduled audit).** Standards used for the evaluation of incoming raw materials are not adequately maintained. The raw materials and finished goods from outside source receiving procedures describes the methods for receipt and sampling of raw material. The document references the receipt and sampling of raw material and secondary reference standards. The QA evaluation and release is recorded on the raw materials & finished goods quarantine release form - shipment damage. The form includes logged and evaluation criteria such as appearance texture, smell, taste, identification testing and release from quarantine. Review of reference standards in the incoming material receiving area found that there were several standards that had receipt dates of 2010. Review of associated COA for the materials found that one sample had passed the expiration date by 2 years and was still being used for material evaluation.
MS7	**Has the factory determined at least one test to verify the identity of a dietary ingredient?** *111.75(a)(i)*	3	3	Y	0		All incoming materials are subject to QC identity testing using NIR assay.	3	3	Y	0		All incoming materials are subject to QC identity testing using NIR assay.
MS8	**For other components, has the factory confirmed the identity and component specification by testing or supplier certificate of analysis (COA)?** *111.75(a)(2)(I,ii)*	2	2	Y	0		Incoming components are received and accepted with Associate Certificate of Conformance.	2	2	Y	0		Incoming components are received and accepted with Associate Certificate of Conformance.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
MS9	**Has the supplier been qualified and is the suppliers COA periodically re-confirmed?** *All raw materials must be tested (all tests required for release as listed on the specification that the Vendor CoA is used for test information instead of testing by the company) at least once annually to score YES. 111.75(a)(A,B,C,D,E)*	3	3	Y	0		Suppliers are subject to a qualification process for each material being supplied, utilizing self audit vendor questionnaires and on-site audit of contract manufacturers. Raw materials are qualified with three lots and the Certificates of Analysis are verified through confirmation testing by outside contract testing laboratories on an annual basis. The vendor and material approval qualification matrix was provided for review.	3	3	Y	0		Suppliers are subject to a qualification process for each material being supplied, utilizing self audit vendor questionnaires and on-site audit of contract manufacturers. Raw materials are qualified with three lots and the Certificates of Analysis are verified through confirmation testing by outside contract testing laboratories on an annual basis. The vendor and material approval qualification matrix was provided for review.
	Production System												
	Subpart E – Requirements to Establish Production and Process Control Systems												
PS1	**Is there a production and process control system that covers all stages of manufacturing dietary supplement quality as specified in the master manufacturing record?** *111.55, 111.60*	3	3	Y	0		Manufacturing control is performed and documented in the weighing, blending, tablet encapsulation, extrusion and manufacturing records. The records include production specifications, manufacturing instructions, procedure completion documentation and in-process and final product testing results.	3	3	Y	0		Manufacturing control is performed and documented in the weighing, blending, tablet encapsulation, extrusion and manufacturing production batch records. The documentation includes production specifications, manufacturing instructions, procedure completion documentation and in-process and final product testing results.
PS2	**Has the factory established a specification for each step in the manufacturing process where control is necessary?** *111.70(a)*	3	3	Y	0		Documented specifications with acceptance criteria have been established for the weighing and tablet encapsulation, extrusion and packaging processes.	3	3	Y	0		Documented specifications with acceptance criteria have been established for the weighing and tablet encapsulation, extrusion and packaging processes.
PS3	**Does the factory perform inline inspections?** *Review the factory's documented inline inspection procedure. The document must exist and observed to be implemented to receive a YES.* *Implementation Guidance*	3	3	Y	0		In-line production inspections are performed and documented during both tableting and packaging operation on the quality control sheet. Tablet checks include time, weight, hardness and friability. The packaging checks include the date, time, label, lot number and bottle count. In-process checks are performed during the extrusion steps and include date, time label, lot average weight of 10 chews and water activity. Periodic QA checks during packaging are performed and documented on the Quality control finished goods form which includes the time, date, label, lot, cup, bag, jar, package weight and QC verified signature. All in-process checks are documented and recorded in the associated batch record.	3	3	Y	0		The tableting operation includes in-line production inspections and checks are performed and documented during both tableting and packaging operation on the quality control sheet. Tablet checks include time, weight, hardness and friability and the packaging checks include the date, time, label, lot number and bottle count. The soft chew operation includes checks during the extrusion steps and include date, time label, lot average weight of 10 chews and water activity. Periodic QA checks during packaging are performed and documented on the Quality control finished goods form which includes the time, date, label, lot, cup, bag, jar, package weight and QC verified signature. All in-process checks are documented and recorded in the associated batch record.
PS4	**Has the factory established component specifications that include identity testing and possible contaminants to ensure the quality of the dietary supplement?** *111.70(b)(1,2,3)*	3	3	Y	0		Component and material specifications include visual - color, clarity, odor, micro, weight and water activity.	3	3	Y	0		There are documented material specifications that include characteristics such as visual - color, clarity, odor, microbiological, weight and water activity.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
PS5	**Has the factory established in-process specifications for each step in the manufacturing process to ensure quality of the dietary supplement and limit contamination?** *111.70(c)(1)*	3	3	Y	0		There are documented specifications that include dimensions such as tablet weight, hardness and friability evaluation.	3	3	Y	0		The tablet and the soft chew products have documented specifications that include dimensions such as tablet / chew weight, hardness and friability evaluation.
PS6	**Has the factory documented the basis for these specifications with quality control personnel approval?** *111.70(c)(2)*	2	2	Y	0		The quality department is involved in the establishment and the monitoring of in-process specifications and inspections.	2	2	Y	0		The quality department is involved in the establishment and the documented monitoring of in-process specifications and inspections.
PS7	**Have product specifications been developed for the quality of the finished batch of the dietary supplement with contaminant limits, if applicable?** *111.70(e)*	3	3	Y	0		Finished product specs are recorded on the QC analytical & inspection report form included in the production record. Specs include visual, analyses - total plate count, enterobacteria, yeast & mold, E.coli and salmonella.	3	3	Y	0		Finished product specifications are recorded on the QC Analytical & Inspection Report form. The form is included in the production record. Specifications include visual, analyses - total plate count, enterobacteria, yeast & mold, E.coli and salmonella.
PS8	**If the factory receives a product for packaging have they established specifications for identity and consistency with its purchase order?** *111.70(f)(g)*	2	0	N/A	2		The producer does not receive product for packaging, however retail packaged biscuits, chews and tubes products are received from contractors, are already packaged. The receiving record includes an evaluation of incoming product against documented specifications.	2	2	Y	0		The producer does not receive product for packaging, however prepackaged retail biscuits, chews and tube products are received from contractors. The receiving record includes an evaluation of incoming product against documented specifications.
PS9	**Are quality control personnel monitoring in-process steps and detecting any deviations?** *111.75(b)(1)(2)*	3	3	Y	0		The QA department is involved in reviewing all manufacturing blending, tablet compression, extrusion and packaging steps. There is a reporting procedure with deviation reports reviewed and approved by the QA department. The deviation / OOS log with requested OOS & deviation reports was provided for review.	3	3	Y	0		The QA department is responsible for performing a documented review of all manufacturing blending, tablet compression, extrusion and packaging records. There is a reporting procedure for the management of in-process deviations. The process is managed and approved by the QA department. The deviation / OOS log with requested OOS & deviation reports was provided for review.
PS10	**From a subset of finished dietary supplement batches (using statistical sampling), does the factory confirm with quality control personnel approval that the product(s) meet specification?** *111.75(c)(1)(2)(3)(4)*	3	3	Y	0		QA / QC evaluation and release are recorded on the QC analytical & inspection report that is included in the production record. The release to stock / shipment and the release notification to production / warehouse is recorded on the inspection report.	3	3	Y	0		QA / QC evaluation and release are recorded on the QC analytical & inspection report that is included in the production record. The release to stock / shipment and the release notification to production / warehouse is recorded on the Inspection Report.
PS11	**If the factory has exempted a product specification (no valid method), has the reason for the exemption been documented?** *111.75(d)(1)(2)*	2	0	N/A	2		The producer has not exempted any product specifications from testing.	2	2	Y	0		The producer has not exempted any product specifications from testing.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
PS12	**Does the factory conduct a visual inspection before packaging or labeling a product?** *Look for a controlled example with lot code printed on the label in the batch record that demonstrates what label was actually run with each lot to determine if this requirement has been met. 111.75(e)(f)(g)*	3	3	Y	0		The producer performs visual inspection and records on the packaging check-off sheet. The inspection includes packaging, lids, defects, lid and labels.	3	3	Y	0		The producer performs a visual inspection of packaging components and records the results on the packaging check-off sheet. The inspection includes verification of packaging, lids, defects, lid and labels.
PS13	**Has the finished dietary supplement met the specification using scientifically valid methods?** *111.75(h)(1)(2)(i,ii,iii,iv,v)*	3	3	Y	0		The component and product evaluation methods include visual and AOAC methods.	3	3	Y	0		The component and product evaluation and testing procedures include visual and recognized AOAC methods.
PS14	**Is there a corrective action when a specification is not met?** *111.75(h)(2)(vi)*	3	3	Y	0		The Quality control on deviations and out of specification investigations and documentation procedure applies to variances from raw material or finished good specifications.	3	3	Y	0		The Quality Control on Deviations and Out of Specification (OOS) Investigations and documentation procedure describes the investigative process and development of corrective actions for out of specification conditions. During the audit there were no OOS events to date to review for conformance.
PS15	**For products not meeting specification, are they rejected?** *111.77(a)(b)(c)*	3	3	Y	0		Material rejection is an option if the investigation and conclusion support this disposition.	3	3	Y	0		Procedurally, material rejection is an option if the investigation and conclusion support this disposition. During the audit there were no OOS events to date to review for conformance.
PS16	**Is the factory collecting representative samples of components, in-process material, subset of finished batches from each lot?** *111.80(a)(b)(c)(d)(e)*	2	2	Y	0		Samples of raw materials are obtained during material receipt and retained on-site for a minimum of one year past the product expiration, for which it is used.	2	2	Y	0		Samples of raw materials are obtained upon material receipt into the facility. The samples are retained on-site for a minimum of one year past the product expiration date.
PS17	**Is the factory collecting a reserve sample and retaining it for a defined period?** *111.83(a)(b)(1)(2)(3)(4)*	2	2	Y	0		Reserve samples are collected and retained for at least four years past product expiration. Review of the retention area observed samples present to support adequate storage.	2	2	Y	0		Reserve samples are collected and retained for at least four years past product expiration. Review of the retention storage area observed representative samples meeting the required storage period.
PS18	**Are quality control personnel conducting a material review and approving any deviations or reprocessing?** *111.87, 111.90*	3	3	Y	0		The QA department performs review of both manufacturing and packaging records upon completion of the associated steps. The review is documented in the records and includes review of noted deviations - unplanned and planned.	3	3	Y	0		The QA department performs review of both manufacturing and packaging records upon completion of each manufacturing step. The review is documented in the batch record and includes a review of noted deviations - unplanned and planned.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
PS19	**Are records being kept for all documents collected under this Subpart E?** *111.95*	3	3	Y	0		All production and support related records are retained and available for review on-site, for at least one year past the product expiration date.	3	3	Y	0		All production and support related records are retained on-site for at least one year past the product expiration date. All requested records were provided for review during the audit.
	Subpart H – Production and Process Control System – Requirements for the Master Manufacturing												
PS20	**Does the master manufacturing record contain a list of components, weights, overages, theoretical yield, specification for each process step, sampling procedures and any deviations along with corrective actions and procedures for testing?** *111.210*	3	0	N	0	Major	**Major ca-m02-2014-gar issued in PS20.** The ingredients used during the product blending step, do not accurately reflect the ingredient statement listed on product retail packaging. Review of selected deviation records observed several situations where the specified ingredient, Kaolin, was not added during product blending. Subsequent comparison of the product label ingredient statement found Kaolin to be included as an ingredient. This observation was noted for approximately 6 different products manufactured during May 2014.	3	3	Y	0		The master manufacturing record (MMR) includes a formulation sheet, with information such as the batch size, blend instructions, quality control in-process check sheet, labels, final batch summary sheet, packaging check off sheet, formulation analysis and the QC analytical & inspection report. Review of sample formulation sheets and corresponding labels found ingredients to correspond. In the event that formulation changes are necessary, the producer has a documented Product Formulation Development and Approval Procedure that includes the method for developing and changing product formulations. The changes are recorded on the Product Change Control Form that includes the description, justification and change approval.
	Subpart K – Production and Process Control System: Requirements for Manufacturing Operations												
PS21	**Do procedures for the manufacturing operation include defined processes, contamination prevention including metals or other foreign material, identifying processing lines and final product disposition?** *Metal Detectors must be challenged with Ferrous, Non-Ferrous and SS samples on a periodic basis to score YES. Metal Detectors must be calibrated at least annually (typically done by an outside firm). It is also acceptable if the metal detector is located on the packaging line, however the same criteria for verification exists. 111.353, 355, 360, 365, 370, 375*	3	3	Y	0		The producer has performed risk assessments for production processes that are documented in HACCP plans. The assessments include evaluation of potential contamination issues. The processes evaluated include soft chew, powder, contracted manufacturer and tableting. The CCPs identified include metal detection, microbiological and water activity. Additional measures include the use of mesh screens during the blending process. Metal detectors on the packaging lines are in the process of being installed and qualified at the time of the audit.	3	3	Y	0		The producer has performed risk assessments (HACCP) for all product categories. The assessments include evaluation of potential contamination issues. The processes evaluated include soft chew, powder, contracted manufacturer and tableting. The CCPs identified in the assessments include metal detection, microbiological analysis and water activity. Additional control measures include the use of mesh screens during the blending process.
PS22	**Are machines, equipment, fixtures and tools suitable to produce clients product?** *Look at the product(s) label and determine if the factory has all of the necessary equipment, etc. to consistently produce.* *Implementation Guidance*	3	3	Y	0		The blending, compression, extraction and the filling and packaging equipment used in the facility are constructed with product contact surfaces composed of smooth, cleanable plastic and stainless steel adequate in design and function to manufacture and package the products under review.	3	3	Y	0		The blending, compression, extraction and the filling and packaging equipment used in the facility is constructed with product contact surfaces composed of smooth, cleanable plastic and stainless steel adequate in design and function to manufacture and package the products under review.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
PS23	**Is there a formal documented preventive maintenance program in place?** *Request and review preventive maintenance program documentation. This should include all machinery, maintenance plans and schedule timing.* *Implementation Guidance*	3	3	Y	0		The producer has dedicated maintenance staff for the oversight of process equipment maintenance. The maintenance & sanitation of equipment program includes a maintenance schedule including, daily, weekly, monthly, quarterly and annual maintenance activities. Selected process equipment maintenance records were reviewed and found to be current and complete.	3	3	Y	0		The producer has dedicated maintenance staff for the oversight of process equipment maintenance. The Maintenance & Sanitation of Equipment Program includes a maintenance schedule with daily, weekly, monthly, quarterly and annual maintenance activities. Selected process equipment maintenance records were reviewed and found to be current and complete.
PS24	**Are documented PRODUCTION procedures or instructions present at each production operation or line?** *While on the production floor look for production procedures at each operation or production line. Must be available and consistent with the language of the operators to receive a YES.* *Implementation Guidance*	1	1	Y	0		Production procedures are included in binders located in production areas in satellite sub binders and in production batch records.	1	1	Y	0		Production procedures are included in binders located in production areas in satellite sub binders and in production batch records.
	Packaging System												
	Subpart L – Production and Process Control System: Requirements for Packaging and Labeling Operations												
PA1	**Is the inventory control system systematic and computerized?** *Verify that the inventory control system is computerized. Must be to receive a YES or Otherwise N/A is the system is manual but systematic.* *Implementation Guidance*	3	3	Y	0		The producer utilizes DataPro for computerized inventory control management of materials, components and finished product.	3	3	Y	0		The producer utilizes DataPro for computerized inventory control management of materials, components and finished product.
PA2	**Does the packaging operation meet written specifications and is there reconciliation of packaging and labels?** *111.410*	3	3	Y	0		The issuance and use of labels is documented on the label control form included in the production record.	3	3	Y	0		The issuance and use of labels is documented on the Label Control form included in each production record.
PA3	**Are there documented investigations when yields are not met for the above specifications?** *Implementation Guidance*	3	3	Y	0		The producer calculates production yields in the production record with OOS ranges at 95-100%. Investigations are documented according to the deviation procedure. Selected deviation reports were provided for review and found to be current and complete.	3	3	Y	0		The producer calculates production yields in the production record with OOS ranges at 95-100%. Investigations are documented according to the deviation procedure. Selected deviation reports were provided for review and found to be current and complete.
PA4	**Is the packaging operation as specified in the master manufacturing record?** *111.415*	3	3	Y	0		Based on observation and records reviewed the packaging operation was observed to be performed as described in the manufacturing record.	3	3	Y	0		Based on observation and records reviewed the packaging operation was observed to be performed as described in the manufacturing record.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
PA5	**Is there physical or spatial separation of the packaging line from other operations and is filling and packaging equipment clean and sanitized and protected from airborne contamination?** *111.415(a)(b)(c)(d)*	3	3	Y	0		Production and packaging equipment are adequately segregated and identified. There are dedicated rooms and isolation using permanent walls and doors. All packaging equipment is subject to cleaning & sanitization prior to use. Cleaning records were provided and found to be complete. There were no obvious potential contamination issues observed.	3	3	Y	0		Production and packaging equipment are adequately segregated and identified. There are dedicated rooms with process segregation using permanent walls and doors. All packaging equipment is subject to cleaning & sanitization prior to use. Cleaning records were provided and found to be complete. There were no obvious potential contamination issues observed.
PA6	**Is there a procedure for disposing of labels that are obsolete or incorrect?** *111.415(h)*	3	3	Y	0		The producer has a documented procedure for disposing of obsolete or incorrect labels. The procedure includes defacing the labels and completing forms to verify the adequate destruction of the labels.	3	3	Y	0		The producer has a documented procedure for disposing of obsolete or incorrect labels. The procedure includes defacing the labels and completing forms to verify the adequate destruction of the labels.
PA7	**Does quality control personnel approve or reject repackaging or relabeling (rework/reprocessing) of product?** *111.420(a)(b)(c)*	3	3	Y	0		The Quality department is responsible for the review, approval and verification of packaging or product relabeling activities.	3	3	Y	0		The Quality department is responsible for the review, approval and verification of packaging or product relabeling activities.
PA8	**Are iron containing products (containing more than 250 mg) packaged in certified for child-resistant containers? N/A if no iron containing products are produced or iron levels are below the 250 mg level)** *Public law 110-314*	3	0	N/A	3		No iron containing products intended for human consumption are produced or packaged at this facility.	3	0	N/A	3		No iron containing products intended for human consumption are produced or packaged at this facility.
	Laboratory System												
	Subpart D – Equipment and Utensils												
LS1	**Are there written procedures for maintenance and calibration of laboratory instruments and equipment?** *111.25(a)(b)*	3	3	Y	0		There are documented procedures that describe the maintenance and calibration of laboratory instruments and equipment.	3	3	Y	0		There are documented procedures that describe the maintenance and calibration of laboratory instruments and equipment.
LS2	**Are appropriate standards, reference materials and calibration standards readily available and properly certified?** *Review standards to which calibrations are being conducted. Ensure they are appropriate.* *Implementation Guidance*	3	3	Y	0		Standards in use in the lab include scales and thermometer standards. The standards reviewed were found to be NIST traceable.	3	3	Y	0		Standards in use in the lab include scales and thermometer standards for calibration. The standards reviewed were found to be NIST traceable.

	CRITERIA / 21 CFR Part 111 et al.	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS	Total Possible Score	Points Scored	Yes/ No	N/A	Major/ Minor	COMMENTS
	Subpart F – Production and Process Control System: Requirements for Quality Control												
LS3	**Are quality control personnel approving all processes, specifications, procedures, deviations, tests, equipment calibration, conducting material review, approving/rejecting material, approving master manufacturing record and production batch, approving/rejecting dietary supplement returns and conducting product complaint analyses?** *111.103, 105, 110, 113, 117, 120, 123, 127, 130, 135*	3	3	Y	0		The QA department has oversight and review authority over all of the listed documents and records. Based on review of selected Quality System records, there was evidence of documented QA review and approval of production documents, deviations, complaints, specifications and OOS.	3	3	Y	0		The QA department has oversight and review authority over all of the listed documents and records. Based on review of selected Quality System records, there was evidence of documented QA review and approval of production documents, deviations, complaints, specifications and OOS.
LS4	**Does written documentation exist for the items in LS3 above?** *111.140*	3	3	Y	0		Requested documentation such as production records, MMRs, analytical methods and testing, specifications, deviations, customer complaints, OOS and calibrations were provided for review.	3	3	Y	0		Requested documentation such as production records, MMRs, analytical methods and testing, specifications, deviations, customer complaints, OOS and calibrations were provided for review.
LS5	**Is there a quality control operation including Quality Assurance having the final release authority?** *Adequate controls must be in place to ensure that finished product cannot be released/shipped without QA approval.111.65*	3	3	Y	0		The producer has an established QA / QC department that has release authority for raw materials, components and finished product. Evidence of review and approval was observed during review of batch records and incoming raw material receipt records.	3	3	Y	0		The producer has an established QA / QC department that has release authority for raw materials, components and finished product. Evidence of review and approval was observed during review of batch records and incoming raw material receipt records.
	Subpart J – Production and Process Control System: Requirements for Laboratory Operations												
LS6	**Does the factory have control procedures, including sampling plans, criteria for reference materials and specifications, scientifically valid test methods, etc.?** *Determine if the methods are documented as being validly sound and if the rationale used is appropriate.111.310, 315, 320, 325*	3	3	Y	0		The producer has documented controlled incoming material and finished product specifications with associated sampling instructions. The specifications reference the analytical methods to perform. The methods used are documented AOAC methods.	3	3	Y	0		The producer has documented controlled incoming material and finished product specifications with associated sampling instructions. The specifications reference the analytical methods to perform. The methods used are documented AOAC methods.

Retail Factory Audit Report
Dietary Supplements
Score Matrix

	System	Score	Possible Number of Points	Points Earned	Number of Questions Answered No	Major NC's	Minor NC's
QS	Quality System	100.0%	50	50	0	0	0
FE	Facilities and Equipment	91.3%	69	63	2	0	2
MS	Material and Supplier Management	76.9%	26	20	2	0	1
PS	Production System	95.1%	61	58	1	1	0
PA	Packaging System	100.0%	21	21	0	0	0
LS	Laboratory System	100.0%	18	18	0	0	0
	Checklist SCORE:	82.88%	245	230	5	1	3
Based on Major NC, a Follow-up Audit is Recommended.							

GRADE	SCORE
Green	80 to 100
Yellow	60 to 79
Red	0 to 59

Retail Factory Audit Report
Dietary Supplements
Follow-up Score Matrix

	System	Score	Possible Number of Points	Points Earned	Number of Questions Answered No	Major NC's	Minor NC's
QS	Quality System	100.0%	50	50	0	0	0
FE	Facilities and Equipment	91.3%	69	63	2	0	2
MS	Material and Supplier Management	76.9%	26	20	2	0	1
PS	Production System	100.0%	65	65	0	0	0
PA	Packaging System	100.0%	21	21	0	0	0
LS	Laboratory System	100.0%	18	18	0	0	0
	Checklist SCORE:	89.18%	249	237	4	0	3
Audit Result Acceptable							

GRADE	SCORE
Green	80 to 100
Yellow	60 to 79
Red	0 to 59