

**GMA Supplier Audits for Food Excellence (SAFE)
Audit Checklist #8BAKWP**

Supplier Information

Plant Name: Greenwood Associates Inc. - Chicago
Address: 4401 S. Oakley Avenue

City: Chicago
State/Province: IL
Country: USA
Postal Code: 60609
Closest Major Airport *: Chicago-Midway / Chicago - O'Hare

Parent Organization (if applicable)

Company Name: Greenwood Associates Inc.
Address:

P.O. Box:
City:
State/Province:
Country:
Postal Code:
Company Public Web Site:

Plant Contact Information

Job Title/Position	Name	Telephone	Fax	Email Address
Plant Manager:	Matt Martens	(773) 579-1291	(773) 579-1251	mattmartens@juicetyme.com
Quality Manager:	Robert Bundy	(773) 579-1291	(773) 579-1251	rbundy@juicetyme.com

Current Audit Information

External ID #:
Audit Date: Feb 14, 2011
Auditor Name: Eilleen McCulloch
Type of Audit Performed: Express Food Safety

RAP Audit Information

Auditor Name:	Eilleen McCulloch
Facility Name:	JuiceTyme
Facility Address:	4401 South Oakley Ave.
Facility City:	Chicago
Facility State/Province:	Illinois
Facility Area / Region:	Midwest

Facility Country:	USA
Facility Postal Code:	60609
Identify major changes made to management, facilities or policies since the last SAFE audit::	None
Identify status of previous deficiencies noted in previous SAFE audit report::	The plant was last audited in 2009.
Is the facility required to be registered with the U.S. FDA?:	YES
Is the facility registered with the U.S. FDA?:	YES
Does this facility audit their supplier either through a first/second/third party audit?:	
Identify the Standard Owner (e.g., BRC, SQF, IFS, etc.):	Not Applicable
What other type of audit has been conducted at this facility (e.g., Social Responsibility, FSIS, Humane Slaughter, etc.):	None
Overview of Site, Operation and Scope of Products Produced:	The plant, JuiceTyme, produces products on their own for their own customers. They also produce product on behalf of Greenwood Associates The plant products produced for Greenwood include drums and pails of juice concentrates. The materials for the concentrations used are from throughout the world.
Products Produced:	Juice concentrates in 55 gallon drums and 5 gallon pails.
Processing Method:	Pumping and filling.
Type of Primary Packaging (e.g., poly, metal cans, aseptic, etc.):	Drums and Pails.
Sizes of Primary Packaging:	55 gallon and 5 gallon
New Product(s) Offering:	None
Channels of Trade (Retail, Wholesale, International, etc.):	The products are offered to other food manufacturers.
Hours of Operation:	8am to 3pm; 5 days per week
Months of Operation (e.g., January - March; January - December):	January - December
Structure Size, Construction and Design:	The area for Greenwood associates is limited to a tank, pump and CIP tank.
Year Built:	Near 1960
Year(s) Updated:	n/a
Size of Facility:	40,000 square feet at Juice Tyme; Approximately 600 sq. ft for manufacture of Greenwood Associates products, another 1000 sq. ft of storage of Greenwood Associates raw material and finished goods.
Number of Employees:	12 at Greenwoos Associates; 40 total at Juice Tyme with 4 being involved in Greenwood Associates Products.
Property Size:	4 acres and a cold storage warehouse.
Neighboring Land Use:	The area is surrounded by small retail shops and other manufacturing facilities.
Building Materials, Exterior Walls:	The exterior of the plant is corrugated material.
Building Material, Interior Walls:	FRP panel and sheathing
Building Material, Floors:	Epoxy resin, concrete

Building Material, Exterior Roof:	Sheet metal pitched roofing
Building Material, Interior Ceiling:	Drop accoustic tile panels
Areas of the Plant Excluded from the Audit:	All JuiceTyme processes are excluded. The audit encompasses the warehouse, Greenwood Associates manufacturing area, and support areas.
Date of Audit Exit Meeting:	Feb 15, 2011
Length of Audit:	2.5 days
Facility Personnel:	Robert Bundy QA Manager, JuiceTyme; Steve Herman, Regulatory Greenwood Associates.
Exit Interview With:	Robert Bundy, Steve Herman
Date of Last SAFE Audit:	Feb 17, 2011

Executive Summary - Part 1

Auditor Judgement Summary		Auditor Judgement					
Category	Section	Fully Meets	Substantially Meets	Partially Meets	Does Not Meet	Critical Failure	Not Applicable / Auditable
1.0 MANAGEMENT RESPONSIBILITY	1.1 Management Commitment and Review		✓				
2.0 FUNDAMENTALS	2.1 Infrastructure		✓				
	2.2 Cleaning / Sanitation		✓				
	2.3 Pest Control	✓					
	2.4 Chemical Control		✓				
	2.5 Personnel Practices		✓				
	2.6 Training & Education		✓				
	2.7 Handling Storage & Delivery	✓					
	2.8 Vendor Approval	✓					
	2.9 Packaging Approval for Use	✓					
	2.10 Control of Materials	✓					
	2.11 Sanitary Design						✓
	2.12 Traceability and Recall Management	✓					
	2.13 Crisis Management			✓			
	2.14 Food Defense			✓			
	2.15 Monitoring and Calibration of Measurement and Test Equipment						✓
	2.16 Calibration of Laboratory Equipment	✓					
	2.17 Traffic Control						✓
	2.18 Facility Maintenance Program			✓			
3.0 FOOD SAFETY & HACCP SYSTEMS	3.1 Hazard Prevention/HACCP	✓					
	3.2 Microbiological Testing		✓				
	3.3 Analytical Testing for Food Safety and/or Regulatory Compliance						✓
	3.4 Food Allergens and Chemical Sensitivities						✓
	3.5 Foreign (Extraneous) Material Control			✓			
4.0 MANUFACTURING QUALITY SYSTEMS	4.1 Conformance to Customer Specifications	✓					
	4.2 Process Control						✓
	4.3 Inspection & Testing	✓					
	4.4 Control of Non conforming Materials	✓					
	4.5 Good Laboratory Practices			✓			
	4.6 Document Control and Record Retention			✓			
	4.7 Corrective and Preventive Action	✓					
	4.8 Continuous Improvement	✓					
	4.9 Customer / Consumer Communication	✓					
	4.10 Internal Self auditing			✓			
5.0 REGULATORY CONSIDERATION	5.1 Label Control	✓					
	5.2 Regulatory & Industry Compliance	✓					
	5.3 Management of the Regulatory Inspection Process	✓					

1.0 MANAGEMENT RESPONSIBILITY		
Section 1.1 Management Commitment and Review		
	AUDIT ITEM	OBSERVATION
1.1.1	Are proper quality system effectiveness reviews conducted by management?	Yes The plant is has a documented quality policy. The policy is posted in the facility and explained to employees during GMP training. The plant has an organization chart. Quality does report through operations at the senior most levels. The plant has a quality manual which includes the Sanitation, Quality, Regulatory and Food Safety programs for the plant. This manual is reviewed at least annually according to the Quality Manager. The review includes top management.
1.1.2	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has a documented Quality Policy. The plant has an organization structure but the Quality role does report through operations. The plant has a Quality System which is reviewed annually. The previous review was not documented but in looking at the documentation provided it was apparent new policies were added within the last year. Additionally, the top management was knowledgeable of the plant systems.
		Facility's Response to Auditor's Observations
		Greenwood will be modifying its organizational structure in the coming year to separate the quality function from operations. In addition, all reviews of the quality manual, and changes, will be documented.

2.0 FUNDAMENTALS		
Section 2.1 Infrastructure		
	AUDIT ITEM	OBSERVATION
2.1.1	Are floors walls and ceilings including overheads racks etc in good condition	Yes The plant overall was in good condition. The plant had an acoustic tile ceiling and some cuts in the tiles through to the overhead space where present.
2.1.2	Do design and condition of floor drains protect product from potential contamination?	Yes
2.1.3	Is the facility adequately protected from the potential risk of foreign material contamination (for example condensate dust rust peeling paint etc) from overhead equipment pipes or structures?	Yes
2.1.4	Does equipment placement or positioning permit proper cleaning and sanitation?	Yes
2.1.5	Did the inspection of exterior grounds and structures indicate they are maintained to protect against contamination of food or facilities?	Yes Most of the exterior grounds were available for review. Some portions were snow covered and inaccessible.
2.1.6		Yes

	Are exterior grounds graded such that water drains away from the building?	
2.1.7	Are mechanical systems for general heating and cooling humidity control ventilation ammonia control etc protected against potential product contamination?	Yes The plant uses pleated MERV 7 filters.
2.1.8	Are key areas of the facility sufficiently lighted to facilitate cleaning standard operations and quality checks for the particular application?	Yes
2.1.9	Are Food contact surfaces made of materials that are appropriate for the process?	Yes The plant uses standard plastic hosing with clamps for the product lines. The hoses are cut to fit and clamped. One hose had rough edges and was in need of replacement.
2.1.10	Are ingredient and food contact water managed to protect from potential contamination?	Yes The plant uses City of Chicago water. The plant does not have on site filtration systems. The plant uses the city testing and pulls samples annually. The sample tests for 2010 are not yet complete.
2.1.11	Does analytical testing during the previous twelve months indicate ingredient and food contact water comply with regulatory standards?	No. Additional details follow: Previous tests (2010) are not available for review as the sample testing is incomplete. It is unknown when these samples will be completed.
2.1.12	If compressed air and/or food contact gases are used for contact food purposes are they filtered?	N / A The plant does not use food contact compressed air.
2.1.13	Are water systems protected against backflow?	Yes
2.1.14	During the Assessment no improper employee practices were observed that could contribute to potential backflow contamination?	Yes
2.1.15	Do sanitary conditions of restrooms locker rooms and dining/break areas protect product from potential contamination?	Yes
2.1.16	Are employee welfare systems functional for example self closing doors unclogged drains working commodes sinks warm water? <<Guidance: If issues were observed provide further details (what	Yes

	where potential for contamination etc)	
2.1.17	Are hand washing signs posted?	Yes There are two hand wash sinks available near the employee work areas. Hand wash signs are posted at both stations.
2.1.18	Are hand washing stations strategically located available (production entrance restrooms etc) accessible and properly equipped?	Yes
2.1.19	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant is in good hygenic order. The plant receives water from the City of Chicago. The water testing reports are not available. The plant has proper employee welfare areas.
Facility's Response to Auditor's Observations		

Section 2.2 Cleaning / Sanitation		
	AUDIT ITEM	OBSERVATION
2.2.1	Does the facility follow a general cleaning and sanitation program (Master Sanitation Schedule or MSS)?	Yes The plant has a master sanitation list and cleaning instructions for equipment. The plant has tasks scheduled at frequencies of daily, weekly, and monthly.
2.2.2	Does the facility have documented work instructions (SSOPs) for cleaning and sanitation?	Yes
2.2.3	Are cleaning and sanitation efforts effective?	Yes The plant coving, where the floor is meeting the FRP panels, has some build up noticeable.
2.2.4	Does the current condition of processing equipment protect product from potential contamination?	Yes
2.2.5	Are welds and seams of food grade quality for example no tack welds no welding slag and smooth?	Yes
2.2.6	Does the facility have documented work instructions for cleaning and sanitation?	Yes
2.2.7	Does the facility have procedures for the control of brushes and other utensils used for cleaning food contact surfaces?	Yes The procedures for the control of cleaning equipment was not documented. The plant area for Greenwood Associates encompasses relatively few employees, of which, only two perform the sanitation tasks. The plant personnel seemed knowledgeable of the controls required by management.
2.2.8	Are procedures for the control of brushes and other utensils carried	Yes

	out?	
2.2.9	Does the facility conduct inspections and/or testing that monitor and verify cleaning and sanitization activities are effective?	Yes ATP swabs are used to test the effectiveness of sanitation efforts. The limit is 100 light units. Any results out of specification resulted in a re-cleaning of the area.
2.2.10	Does the facility conduct inspections and/or testing that monitor and verify cleaning and sanitization activities are effective?	Yes
2.2.11	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant had cleaning and sanitation program. The plant items on the master sanitation list, floors, walls, ceilings, do not have a cleaning instruction. Equipment does have cleaning instructions. The plant does have personnel which are trained in the sanitation cleaning process and proper use of chemicals. Buildup was seen on the floor coving.
		Facility's Response to Auditor's Observations
		All equipment used for Greenwood will have cleaning instructions. Buildup on the floor coving will be removed.

Section 2.3 Pest Control		
	AUDIT ITEM	OBSERVATION
2.3.1	** Does the facility have a functioning documented pest control program?	Yes. A brief description follows: The plant has a pest management program which includes a map of the devices in the plant, the frequency of inspection for each of the device types, reports on activity found in the devices and pesticides used. Additionally corrective actions to broken devices or unsanitary conditions are documented.
2.3.2	Does the facility utilize contracted services and pest control technicians for its pest control program?	Yes The plant uses a Copesan company to provide pest management services.
2.3.3	Is the contracted pest control company's business license current?	Yes The expiry is December, 2011.
2.3.4	Are pest control company insurance certificates up to date?	Yes The expiry is January, 2012.
2.3.5	Are individual applicator licenses current?	Yes The individuals pest licenses expire in December, 2011.
2.3.6	Does the facility audit contracted Pest Control Company's performance?	Yes
2.3.7	During the inspection of facilities and grounds was the facility free of evidence of current uncontrolled pest activity?	Yes
2.3.8	Is the building exterior protected against rodent	Yes

	and pest entry?	
2.3.9	Is a clear vegetation free perimeter (for example asphalt river rock etc) maintained adjacent to production and storage buildings?	Yes It was difficult to measure the vegetation free zone around the entire plant due to the snow. The majority of the outside of the plant is paved, with only a small vegetation zone.
2.3.10	Are building exteriors free of pest harborage sites for example obsolete equipment storage construction materials un capped piping pallets etc?	Yes
2.3.11	Are building exteriors free of pest harborage sites for example obsolete equipment storage construction materials un capped piping pallets etc?	Yes
2.3.12	Are practices followed that require pest control technicians to examine the insides of all traps/bait stations?	Yes The plant uses bar coding on the interior of the traps which are scanned by the pest control company at each visit.
2.3.13	Are pest control devices inspected at a pre determined frequency?	Yes The devices on the exterior are examined twice per month. The devices on the interior were: traps - twice per month; fly stations as needed.
2.3.14	Are documented corrective actions taken when deficiencies are identified?	Yes
2.3.15	Are only authorized individuals responsible for applying pesticides?	Yes
2.3.16	Are pesticide applications documented in accordance with regulatory requirements?	Yes
2.3.17	If pesticides are stored on site are storage areas secure and restricted against unauthorized access?	N / A
2.3.18	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant has a pest management program which includes a map of the devices in the plant, the frequency of inspection for each of the device types, reports on activity found in the devices and pesticides used. The pest management program is managed by a third party who is licensed. All licenses are current. Additionally corrective actions to broken devices or unsanitary conditions are documented.
		Facility's Response to Auditor's Observations

Section 2.4 Chemical Control

AUDIT ITEM		OBSERVATION
2.4.1	Does the facility have a system in place for the 1) purchase 2) use and 3) isolation of non food grade chemicals from product areas?	Yes The plant has the system to purchase and use and isolate non-food grade chemicals. The QA Manager is charged with the purchases.
2.4.2	Were areas subject to GMP regulations free of uncontrolled non food chemicals?	Yes
2.4.3	Are primary and secondary containers for non food chemicals accurately and legibly labeled?	Yes
2.4.4	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant had a chemical control policy which limited the purchases to few individuals, and left control in the plant to the QA Manager. Only food grade greases were seen in production. No other miscellaneous chemicals were found. The plant has locked cabinets for storage. The plant does not control the chemicals in the offices, which are adjacent to production.
		Facility's Response to Auditor's Observations

Section 2.5 Personnel Practices		
AUDIT ITEM		OBSERVATION
2.5.1	Were GMP instructions and/or protective gear provided to the auditor before access to the facility?	Yes
2.5.2	Is there a policy that complies with governmental regulation addressing the use of hair restraints where food product packaging or ingredients are exposed?	Yes
2.5.3	Do employees visitors and contractors adhere to the hair restraint policy in relevant areas?	Yes
2.5.4	Does the facility have a policy that addresses the wearing of jewelry including body piercings false fingernails fingernail polish watches medical alert identification etc where food products packaging or ingredients are exposed?	No The plant does not have a policy which includes perfumes/colgnes, body piercings, medical alert identifications. Other concepts were within the GMP policy.
2.5.5		Yes

	Do employees visitors and contractors in relevant areas adhere to the jewelry policy?	
2.5.6	Does the facility have a hygiene policy that includes hand washing hand dips and prevention of cross contamination?	Yes
2.5.7	Were employees observed washing their hands thoroughly using soap and warm/hot water before starting work after breaks and after using the restroom?	Yes
2.5.8	Are hand dips and/or hand sanitizers used?	No
2.5.9	Are hand and foot sanitizers at proper concentrations?	N / A The plant does not have hand nor foot sanitizers.
2.5.10	Are all finished product and packaging (including full cases) used exclusively for their intended purposes?	Yes
2.5.11	Does the facility have an employee glove policy including procedures for glove control?	No
2.5.12	Do employees in relevant areas adhere to the employee glove policy?	N / A The facility does not have a glove policy.
2.5.13	Does the facility have a consumption policy that restricts eating drinking and tobacco use in processing and packaging areas?	Yes
2.5.14	Does the facility have a consumption policy that restricts eating drinking and tobacco use in processing and packaging areas?	Yes
2.5.15	Do employees visitors and contractors in relevant areas adhere to the consumption policy?	Yes
2.5.16	Were personal items properly stored away from production or warehouse areas for example sweaters coats literature radios etc?	No. Additional details follow: Personal items were not restricted within the production area.
2.5.17	Do personnel health policies and procedures exist to ensure employees afflicted by	Yes

	illnesses or open wounds have adequate protection or are reassigned?	
2.5.18	Do employees visitors and contractors in food safety sensitive areas adhere to the health policy?	Yes
2.5.19	Does the facility have an apparel policy that protects product from damaged or poorly designed clothing or apparel unsuited for the food manufacturing environment?	Yes
2.5.20	Does the facility apparel policy include restrictions against clothing materials that may cause foreign material contamination?	Yes
2.5.21	Do employees visitors and contractors in food safety sensitive areas adhere to the apparel policy?	Yes
2.5.22	Does the facility have a policy regarding cleanliness of uniforms shoes and outer apparel?	Yes
2.5.23	Does the uniform cleanliness policy include restrictions on wearing company provided uniforms gloves head covering shoes or other specialized clothing when exiting the work area?	Yes
2.5.24	Do all facility employees (full time part time or seasonal) contractors and visitors follow the uniform cleanliness policy by wearing clean outer garments where required and by restricting types of clothing worn in highly sensitive areas?	Yes
2.5.25	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has GMP policies that cover everything except the following: The plant does not have a policy that includes perfumes/colognes, body piercings, nor medical alerts. The plant does not have hand or foot sanitizers, nor a glove policy. Personal items are not restricted within the production area.

	Facility's Response to Auditor's Observations
	GMP policies are being revised to cover perfumes/colognes, body piercings and medical alerts. Restrictions on personal items within the production area are being developed and will be implemented in the near future.

Section 2.6 Training & Education		
	AUDIT ITEM	OBSERVATION
2.6.1	Does the facility provide specialized training to its employees regarding food safety matters for example food defense MSDS (or equivalent) HACCP hygiene cleaning microbiology/swabbing GMPs GMPs etc?	Yes The plant provides GMP training to all 3 operators, MSDS and sanitation to 2 of the 3 operators, and HACCP training to the person who works within the plan. The plant does not provide other training including pest control, food defense or basic microbiology.
2.6.2	Based upon the physical inspection does training appear to be effective?	Yes
2.6.3	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has an orientation for the employees. The plant provides GMP training to all 3 operators, MSDS and sanitation to 2 of the 3 operators, and HACCP training to the person who works within the plan. The plant does not provide other training including pest control, food defense or basic microbiology.
		Facility's Response to Auditor's Observations
		Additional training programs are being developed and will be implemented in the near future.

Section 2.7 Handling Storage & Delivery		
	AUDIT ITEM	OBSERVATION
2.7.1	Does the facility carry out activities designed for the protection and inspection of stored goods?	Yes
2.7.2	Do records indicate storage sites are inspected at a designated frequency?	Yes
2.7.3	Were storage areas found to be in good condition during the physical inspection of the facility?	Yes
2.7.4	Were temperature or humidity sensitive items found to be stored under proper conditions (temperature humidity etc) during the physical inspection of the facility?	Yes
2.7.5	inbound and outbound goods inspected according to established	Yes

	procedures?	
2.7.6	Are all inbound seal numbers cross checked and verified against receiving documents (to include top and bottom bulk carrier ports hatches doors etc)?	Yes
2.7.7	Are there procedures for handling inbound carriers and goods when seals are missing broken or do not match the Bill of Lading?	Yes
2.7.8	Does the facility inspect pallets prior to use for contamination unsanitary conditions and physical damage?	Yes Pallets are inspected in production prior to use.
2.7.9	Does the facility have procedures for the protection of bulk materials during loading and unloading of carriers?	N / A The plant receives juice in drums. The plant has not, for at least the last year, received a bulk tanker.
2.7.10	Were food protection procedures for handling bulk product effective?	N / A
2.7.11	Does the facility track expiration dates of raw materials?	Yes
2.7.12	Does the facility ensure raw materials are protected from deterioration and adulteration while awaiting final storage?	Yes
2.7.13	Does the facility have procedures to ensure finished goods are protected from deterioration and adulteration while awaiting shipment?	Yes
2.7.14	Does the facility have procedures and requirements regarding shelf life and release status of finished goods?	Yes
2.7.15	Does the facility have a stock rotation program for example FIFO Oldest First etc?	Yes
2.7.16	Do stock rotation practices conform to established procedures?	Yes
2.7.17	Are returned goods managed to prevent contamination to themselves the facility	N / A The plant does not accept return goods. Return goods are sent to outside storage where they are evaluated and potentially resold.

	and other products?	
2.7.18	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant carries out activities designed for the protection and inspection of stored goods. Storage sites are inspected at a designated frequency and are found to be in good condition. Temperature sensitive items are stored at proper conditions. Inbound and outbound good are inspected, seal numbers are cross checked and verified. Pallets are inspected in production, prior to use. The plant receives juice in drums. The plant has not, for at least the last year, received a bulk tanker. The plant tracks expiration dates of raw materials, which are protected from deterioration and adulteration while awaiting final storage. Finish goods are protected while waiting shipment, with shelf life and release states verified. The plant does have a stock rotation program. The plant does not accept return goods. Return goods are sent to outside storage where they are evaluated and potentially resold.
		Facility's Response to Auditor's Observations

Section 2.8 Vendor Approval		
	AUDIT ITEM	OBSERVATION
2.8.1	Does the facility have a vendor approval program to prevent purchase of non approved goods?	Yes
2.8.2	Does the facility consider food safety in its vendor approval process?	Yes
2.8.3	Does the facility only accept products/ingredients from pre approved manufacturers?	Yes
2.8.4	Was a recent shipment actually received from a supplier on the Approved Vendor List?	Yes
2.8.5	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant has a vendor approval program and only accepts products/ingredients from pre-approved manufacturers. A shipment was received from a supplier on the Approved Vendor List.
		Facility's Response to Auditor's Observations

Section 2.9 Packaging Approval for Use		
	AUDIT ITEM	OBSERVATION
2.9.1	Does the facility purchase packaging materials based upon written approved specifications?	Yes
2.9.2	Does the facility have procedures to inspect	Yes

	and segregate out of spec packaging?	
2.9.3	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant purchases packaging materials based on written, approved specifications. The plant does inspect and segregate out-of-spec packaging.
		Facility's Response to Auditor's Observations

Section 2.10 Control of Materials		
	AUDIT ITEM	OBSERVATION
2.10.1	Does the facility ensure incoming raw ingredients and processing aids conform to specification?	Yes
2.10.2	Does the facility properly execute release procedures for incoming ingredients and verify whether they are followed?	Yes
2.10.3	Does the facility have procedures that coordinate and confirm specification changes with vendors?	Yes
2.10.4	Does the facility have policies and procedures that address the use of materials intended for rework?	N / A The plant does not perform rework.
2.10.5	Does the facility have procedures that address the storage condition of reworked materials?	N / A
2.10.6	Does the facility have procedures that address the identification and coding of materials intended for rework?	N / A
2.10.7	Does the facility have procedures that address percent of rework that can be added back to the regular formula?	N / A
2.10.8	Does the facility maintain batch formulation records that identify the addition of reworked product?	N / A
2.10.9	Does the facility enforce periodic breaks in the rework cycle?	N / A
2.10.10	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		

	The facility ensures incoming raw ingredients conform to specifications. The plant executes release procedures for incoming ingredients and verify that they are followed. The plant has procedures that coordinate and confirm specification changes with vendors. The plant does not perform rework.
	Facility's Response to Auditor's Observations

Section 2.11 Sanitary Design		
	AUDIT ITEM	OBSERVATION
2.11.1	Does the facility have policies and procedures to review and approve sanitary design of equipment before purchase?	N / A Only a portion of the plant is associated with Greenwood Associates production. This portion is not under remodel. The plant is not adding the any additional lines or processes.
2.11.2	Does the facility have specific policies and procedures regarding sanitation issues during the installation process?	N / A
2.11.3	Does the facility stipulate and verify the sanitary design and installation of newly purchased equipment before it is placed into service?	N / A
2.11.4	When changes are made to existing equipment and/or surrounding structure are obsolete items removed from the area?	N / A
2.11.5	Summary and Comments	
SECTION JUDGMENT:		Not Applicable / Auditable
SECTION SUMMARY:		Only a portion of the plant is associated with Greenwood Associates production. This portion is not under remodel. The plant is not adding the any additional lines or processes.
		Facility's Response to Auditor's Observations

Section 2.12 Traceability and Recall Management		
	AUDIT ITEM	OBSERVATION
2.12.1	Does the facility have a formal Recall Management System?	Yes
2.12.2	To facilitate tracking does the facility require all incoming goods including bulk to be marked by vendors with traceable coding?	Yes
2.12.3	Was a recently received material shipment handled according to	Yes

	procedures that ensure traceability?	
2.12.4	Does the facility have the ability to trace raw materials through to finished product?	Yes
2.12.5	Does the facility have the capability to maintain full traceability where one lot code is commingled with others for example bulk storage common grower fields and/or collection sites etc?	Yes
2.12.6	Is the process for traceability of reworked and/or repacked products documented and implemented?	N / A
2.12.7	Can reworked/repacked product be traced back to the original production lot?	N / A
2.12.8	Does the facility have documented lot coding process?	Yes
2.12.9	Are codes found on raw materials and finished products correct accurate and legible?	Yes
2.12.10	Does the facility conduct routine in house mock recalls for RAW MATERIAL and FINISHED PRODUCT both one step forward and backward?	Yes
2.12.11	Does the facility meet its expectations for percent recovery AND elapsed time?	Yes. A brief description follows: The plant policy states that 100% of finished good units must be found within 2 hours. The last two finished product recalls show this standard is met.
2.12.12	Did the product/ingredient trace exercise performed during the Assessment comply with facility expectations?	Yes. A brief description follows: The plant completed a trace of one lot of 72 drums of lemon concentrate received from a supplier in Ontario. The plant was able to trace the entry into two separate productions, and had one direct sale. The plant traced all materials (100%) of raw and finished goods in less than 1 hour.
2.12.13	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant requires vendors to provide lot coding. Materials are issued to the line by the lot/PO number. The plant is able to trace all materials through to final product. The plant sets their expectations at 100% in less than 2 hours.
		Facility's Response to Auditor's Observations

Section 2.13 Crisis Management

AUDIT ITEM		OBSERVATION
2.13.1	Does the facility have a Crisis Management Program established that includes contingency plans for the continuation of supply to its customers?	Yes. A brief description follows: Greenwood associates has a crisis management program for natural disasters and interruptions in utility services. Greenwood uses a supply network to continue the plan of supply to customers. JuiceTyme does not have a crisis management policy.
2.13.2	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant does have a crisis management or contingency plan for the continuation of the supply to customers. Greenwood Associates uses other supply chain mechanisms for delivering the final product to the customers. The plant, JuiceTyme, does not have a crisis management policy.
		Facility's Response to Auditor's Observations
		Juice Tyme will have a crisis management policy prior to the next audit.

Section 2.14 Food Defense		
AUDIT ITEM		OBSERVATION
2.14.1	Has a Food Defense Assessment been conducted for the facility?	** No The plant has done an in house assessment which includes only minor security items such as building exterior. An all encompassing food defense assessment has not been done.
2.14.2	Has the facility designated individuals who are accountable for coordinating Food (or Product) Defense at the facility	Yes
2.14.3	Has the Food Defense policy or plan been fully implemented at this facility?	Yes
2.14.4	Do procedures restrict EMPLOYEE access to the facility in general (including warehouses) and/or to individual departments inside the facility?	Yes
2.14.5	Do procedures restrict NON employee access to the facility for example visitors service providers truck drivers contractors etc?	Yes
2.14.6	Are Food Defense tools utilized by the facility eg electronic access control picture IDs guard service fencing or restrictions to property self closing doors to plant levels of security clearances cameras or other monitoring devices etc?	Yes Outdoor lighting and identity cards are used by the plant.

2.14.7	During the Assessment were observations of Food Defense activities consistent with the current policy?	Yes
2.14.8	Is the Food Defense policy/program periodically assessed by management for areas of vulnerability including premises products and raw materials that may be at risk?	Yes
2.14.9	Were Food Defense instructions provided to the auditor before given access to the facility?	Yes
2.14.10	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has done an in house assessment which includes only minor security items such as building exterior. An all encompassing food defense assessment has not been done. The plant has a designated person fro coordinating Food Defense at the facility. Employee and NON Employee access is restricted. Outdoor lighting and identity cards are used by the plant as Food Defense tools.
		Facility's Response to Auditor's Observations

Section 2.15 Monitoring and Calibration of Measurement and Test Equipment		
	AUDIT ITEM	OBSERVATION
2.15.1	Does the facility have a calibration program for processing equipment?	N / A The plant does not utilize equipment which requires calibration.
2.15.2	Does the processing equipment calibration program include a list of equipment requiring calibration?	N / A
2.15.3	Does the processing equipment calibration program include calibration frequencies?	N / A
2.15.4	Summary and Comments	
SECTION JUDGMENT:		Not Applicable / Auditable
SECTION SUMMARY:		The plant does not use processing equipment which requires calibration.
		Facility's Response to Auditor's Observations

Section 2.16 Calibration of Laboratory Equipment		
	AUDIT ITEM	OBSERVATION
2.16.1	Does the laboratory equipment calibration program include calibration frequencies?	Yes

2.16.2	Do records for laboratory equipment calibration appear to be complete?	Yes
2.16.3	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant laboratory equipment requiring calibration includes a balance, pH meter, and Brix unit. The devices are measured by the plant staff to determine if the unit is within calibration. The plant uses purchased standards for the pH and Brix, and an outside vendor for the balance.
		Facility's Response to Auditor's Observations

Section 2.17 Traffic Control		
	AUDIT ITEM	OBSERVATION
2.17.1	Does the facility physically segregate raw from processed/finished product to prevent cross contamination between items?	N / A The production space for Greenwood Associates is small. Materials move in and out through two door entrances. The packaging goods are stored separate from food materials.
2.17.2	Does the facility use dedicated equipment to prevent contamination of processing areas?	N / A
2.17.3	Are policies and/or practices in place to minimize cross contamination for example restricted traffic patterns physical partitions separate restrooms uniform policies floor scrubbers use of foot baths/sprays airflow UV sterilizers etc?	N / A
2.17.4	Are existing control measures that reduce potential cross contamination being followed?	N / A
2.17.5	Summary and Comments	
SECTION JUDGMENT:		Not Applicable / Auditable
SECTION SUMMARY:		The production space for Greenwood Associates is a small area within a larger facility.
		Facility's Response to Auditor's Observations

Section 2.18 Facility Maintenance Program		
	AUDIT ITEM	OBSERVATION
2.18.1	Does the facility have a documented corrective and preventive maintenance program?	Yes
2.18.2		

	** Does the corrective and preventive maintenance program require post maintenance sanitation inspection of equipment and/or purging where product contamination may occur prior to reinstatement/start up?	** No The plant does not have a set post- maintenance equipment cleanliness verification. All preventive maintenance is done prior to start up and the line is inspected and sanitized prior to start up.
2.18.3	Are tool carts and/or part carts cleaned between use and/or dedicated to prevent contamination of the processing areas in ready to eat facilities?	N / A The facility is not a ready to eat facility.
2.18.4	Are tool carts and/or part carts cleaned between use and/or dedicated to prevent contamination of the processing areas in ready to eat facilities?	Yes
2.18.5	Did all temporary repairs observed during the Assessment comply with established procedures for example duct tape cardboard string plastic film etc?	N / A No temporary repairs were noted in the audit.
2.18.6	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has a maintenance work order and preventive maintenance program. There is no policy for documenting sanitary conditions immediately following maintenance, however most work occurs off hours. The maintenance areas were clean and tools seen in the production areas were clean. Temporary repairs were not seen in the plant.
		Facility's Response to Auditor's Observations

3.0 FOOD SAFETY AND HACCP SYSTEMS		
Section 3.1 Hazard Prevention/HACCP		
	AUDIT ITEM	OBSERVATION
3.1.1	Does the facility have a documented Hazard Prevention program?	Yes
3.1.2	Is the facility Hazard Prevention program HACCP based?	Yes
3.1.3	Are all products or processes covered under the HACCP/Hazard Prevention program?	Yes
3.1.4	Does the facility have a multidisciplinary HACCP/Hazard Prevention team that is assigned overall responsibility for the	Yes

	Hazard Prevention program?	
3.1.5	Does the HACCP/Hazard Prevention team meet regularly to evaluate the current Hazard Prevention program?	Yes
3.1.6	Has one or more members of the Hazard Prevention team completed a formal HACCP/Hazard Prevention training session?	Yes. A brief description follows:
3.1.7	Do the HACCP/Hazard Prevention plans include 1) product descriptions 2) distribution 3) intended uses and 4) target consumers (channels of trade)?	Yes. A brief description follows: The products include juice concentrates and juice blends. They are shipped frozen and intended to be used by food manufacturers.
3.1.8	Do the HACCP/Hazard Prevention plans include 1) product descriptions 2) distribution 3) intended uses and 4) target consumers (channels of trade)?	Yes
3.1.9	Are process flow diagrams accurate for all HACCP/Hazard Prevention plans?	Yes
3.1.10	Does the facility have a written Hazard Analysis that 1) supports the Hazard Prevention plan and 2) considers the severity and likelihood of occurrence?	Yes
3.1.11	Does the HACCP plan include all key HACCP elements for each CCP?	Yes. A brief description of each key element follows: The CCP for the process was that the plant receives information regarding the pasteurization of the product by their vendors. Additionally the plant receives a COA for each load.
3.1.12	Are audits or reviews of HACCP/Hazard Prevention procedures conducted by the facility to ensure they are executed according to the facility's plan?	Yes
3.1.13	Has the facility validated all critical limits or key elements?	Yes
3.1.14	Are HACCP/Hazard prevention plans periodically reassessed annually and/or in response to changes?	Yes
3.1.15	Were copies of the HACCP/Hazard	Yes

	Prevention plan in use during the inspection current and up to date?	
3.1.16	Are all copies of HACCP/Hazard Prevention plans signed by authorized individuals?	Yes
3.1.17	Are PROCEDURES followed and recorded as specified in HACCP/Hazard Prevention plans?	Yes
3.1.18	Are CORRECTIVE ACTIONS conducted and recorded as specified in HACCP/Hazard Prevention plans?	Yes
3.1.19	Are the VERIFICATION STEPS conducted and recorded as specified in HACCP/Hazard Prevention plans?	Yes
3.1.20	Are reviews of CCP monitoring reports corrective actions and records verification conducted by personnel trained in HACCP/Hazard Prevention?	Yes
3.1.21	Are reviews of CCP monitoring corrective actions and record verification documented as specified by HACCP/Hazard Prevention plans?	Yes
3.1.22	Are HACCP/Hazard Prevention records readily available?	Yes
3.1.23	Were all deficiencies in the execution of HACCP/Hazard Prevention plan resolved when first reported?	Yes.
3.1.24	Were key non management personnel knowledgeable of their responsibility with HACCP/Hazard Prevention programs?	Yes
3.1.25	Is specialized training provided for HACCP/Hazard Prevention operators?	Yes
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The HACCP plan is complete with hazard analysis and control points measure throughout the process. The process steps were complete and the hazards were

identified. If the CCP is not met then the loads are rejected.

Facility's Response to Auditor's Observations

Section 3.2 Microbiological Testing

AUDIT ITEM		OBSERVATION
3.2.1	Does the facility have a microbiological testing program for SANITATION?	No The plant does ATP swabs post sanitation. They are in the process of initiating a post sanitation program which includes microbiology swabs.
3.2.2	Does the facility have a microbiological testing program for ENVIRONMENTAL MONITORING?	No
3.2.3	Does the environmental testing program document corrective actions taken in response to positive results?	N / A
3.2.4	Does the microbiological testing program in ready to eat facilities require that finished product be tested in response to positive environmental results?	N / A
3.2.5	Does the facility have a microbiological testing program for RAW and/or REWORKED MATERIALS?	N / A
3.2.6	Does the facility have a microbiological testing program for WORK IN PROGRESS?	No
3.2.7	Does the facility have a microbiological testing program for FINISHED GOODS?	Yes. A brief description follows: The plant tests product to the specification of the customer. Tests include APC, coliform, E.coli, and yeast/mold. Some pathogen testing is done upon request of the client.
3.2.8	Do the target organisms identified by this facility include all appropriate microorganisms for the product manufactured eg thermophiles (high heat resistant organisms) for low acid products organisms that are indicators of contamination etc?	Yes
3.2.9	Does the microbiological testing program include corrective actions for when out of standard results are found for ingredients or product for example re sampling/re	Yes

	testing protocols are defined and followed?	
3.2.10	Does the microbiological testing program require products and/or raw materials to be held until testing is completed?	Yes
3.2.11	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has microbiological testing of the finished product in accordance with customer specifications. The plant is in the process of initiating a program to test sanitation. This program has just been initiated and results are being gathered to determine limits.
		Facility's Response to Auditor's Observations

Section 3.3 Analytical Testing for Food Safety and/or Regulatory Compliance		
	AUDIT ITEM	OBSERVATION
3.3.1	Does the facility conduct analytical testing as part of its Food Safety or Regulatory Compliance program?	No. Additional details follow: The plant does not perform any analytical testing to meet food safety or regulatory compliance programs.
3.3.2	Does a review of analytical testing records indicate results conform to specifications?	N / A
3.3.3	Are analytical test results used to determine product and ingredient disposition?	N / A
3.3.4	Summary and Comments	
SECTION JUDGMENT:		Not Applicable / Auditable
SECTION SUMMARY:		The plant does not perform any analytical testing to meet any food safety or regulatory programs.
		Facility's Response to Auditor's Observations

Section 3.4 Food Allergens and Chemical Sensitivities		
	AUDIT ITEM	OBSERVATION
3.4.1	Are materials used or stored at this facility that are recognized by the country of product origin OR destination or by the customer as food allergens or chemical sensitizing agents?	No. Additional details follow: Greenwood Associates does not use any allergens.
3.4.2	Does the facility execute a documented Allergen Control plan to eliminate or minimize risk of product exposure to known allergens and	N / A

	sensitizing agents?	
3.4.3	Does the facility's allergen control procedure list allergens and sensitizing agents for ALL ingredients and materials used in the plant?	N / A
3.4.4	Does the allergen control procedure provide for updates to the allergen list when new allergens and allergenic sources are brought to the facility?	N / A
3.4.5	Are protective measures and corrective actions taken to protect other products from allergens/sensitizers during product changeover or equipment cleaning?	N / A
3.4.6	Are special precautions followed to prevent inadvertent cross contact by allergens and sensitizing agents through the entire process (that is from receiving to processing to warehousing to shipping)?	N / A
3.4.7	Does the facility dedicate people and equipment (utensils scoops buckets clothing/uniform etc) to specific allergen/sensitizer related products or processes?	N / A
3.4.8	Does the facility comply with its production schedules change overs and cleaning regimens that prevent allergen/sensitizer cross contact issues?	N / A
3.4.9	Does the facility conduct post cleaning tests of shared equipment to verify absence of allergens prior to processing product of a different formula?	N / A
3.4.10	Is the equipment inspected by someone other than the individual who cleaned the equipment?	N / A
3.4.11		N / A

	Are specific actions required when cross contact with an undeclared allergen is suspected?	
3.4.12	Are corrective actions documented for suspected cross contact with an undeclared allergen?	N / A
3.4.13	Are procedures in place that ensure all allergens and sensitizing agents are correctly displayed on product labels in accordance with regulatory requirements?	N / A
3.4.14	Does the allergen control program include provisions and controls for the rework of products and ingredients containing allergens or sensitizing agents?	N / A
3.4.15	Has the facility identified specific re entry points on each production line for reworked products and ingredients containing allergens or sensitizing agents?	N / A
3.4.16	Are reworked products containing allergens/sensitizers clearly differentiated from regular rework?	N / A
3.4.17	Summary and Comments	
SECTION JUDGMENT:		Not Applicable / Auditable
SECTION SUMMARY:		Greenwood Associates does not utilize any allergens.
		Facility's Response to Auditor's Observations

Section 3.5 Foreign (Extraneous) Material Control		
	AUDIT ITEM	OBSERVATION
3.5.1	Are foreign material control devices utilized to protect ingredients bulk items work in progress and finished goods from extraneous materials?	Yes
3.5.2	Does the facility regularly monitor its foreign material control devices?	Yes The plant monitors the magnets.
3.5.3	Does the facility have metal detector or X ray procedures that include test frequency test piece	N / A The plant is a fluid juice manufacturer and does not use metal detection or x-ray.

	specifications and requirements of an acceptable verification test?	
3.5.4	From observation do employees comply with established techniques regarding use and testing of foreign material control devices?	Yes
3.5.5	Are facility inspections designed to detect metal to metal contact points equipment wear and missing nuts or bolts that could result in foreign material contamination in on or above product surfaces?	Yes This is done during in plant inspections.
3.5.6	Are measures controls or devices in place to prevent wood contamination (slip sheets vibratory screens etc)?	No
3.5.7	Has the facility implemented glass and brittle plastic control procedures?	Yes
3.5.8	Does the facility have special procedures when glass must be used in processing areas?	Yes The facility performs routine glass audits.
3.5.9	Is glass lighting properly shielded?	Yes
3.5.10	Does the glass/brittle plastic procedure define accountabilities for line start up following a breakage incident?	Yes Glass breakage is reported to supervisors and the line is shut down.
3.5.11	Does the facility comply with its glass and brittle plastic procedures?	Yes
3.5.12	Does the facility have documented procedures regarding use and control of food grade lubricants?	No The plant reported that they use food grade lubes in the plant and only food grade lubes were found in the plant.
3.5.13	Did all food grade lubricants appear to be appropriately applied?	Yes
3.5.14	Are exposed foods or food contact surfaces located below lubricated mechanisms protected from possible contamination?	Yes
3.5.15	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets

SECTION SUMMARY:	The plant has a magnet to detect metals in the process. Metal to metal contacts, nuts, and bolts are inspected prior to start up. The plant also restricts glass in the plant and audits glass routinely. The glass lights in the plant are shielded from shattering. Broken glass is reported to supervisors. The plant does not document the lube policy but reported they only use food grade lubes. Only food grade was found in the plant.
	Facility's Response to Auditor's Observations

4.0 MANUFACTURING QUALITY SYSTEMS

Section 4.1 Conformance to Customer Specifications

	AUDIT ITEM	OBSERVATION
4.1.1	Does the facility have a system for 1) receiving 2) implementing and 3) controlling customer specific standards?	Yes
4.1.2	Does the facility utilize co manufacturers to make or produce any portion of a customers' product?	No. Additional details follow: The plant does not use a co-manufacturer.
4.1.3	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		Greenwood Associates has specifications for each of the products they manufacture. The products are made at JuiceTyme by JuiceTyme employees with Greenwood Associates overseeing the process records, sampling and shipping records.
		Facility's Response to Auditor's Observations

Section 4.2 Process Control

	AUDIT ITEM	OBSERVATION
4.2.1	** Does the facility execute procedures to specifically designed to ensure finished product weight or volume complies with Customer and regulatory requirements?#10	N / A The facility does not sell by weight. The facility check quality on single batches.
4.2.2	In addition to weight/volume control are additional processes employed to control other variables such as temperature flow rate viscosity granulation pH in line moisture weight control organoleptic checks etc	N / A The facility does not sell by weight.
4.2.3	Are up to date documented processing and quality procedures readily accessible to key operators?	N / A
4.2.4	During the Assessment did finished product net	N / A The facility does not sell by weight.

	weights comply with label declarations?	
4.2.5	Summary and Comments	
SECTION JUDGMENT:		Not Applicable / Auditable
SECTION SUMMARY:		The facility does not sell by weight.
		Facility's Response to Auditor's Observations

Section 4.3 Inspection & Testing		
	AUDIT ITEM	OBSERVATION
4.3.1	Does the facility have a finished goods inspection program to ensure product conformance to internal or customer specifications?	Yes Product is tested to customer and internal specifications.
4.3.2	Does the facility conduct organoleptic (sensory) evaluations on products?	Yes
4.3.3	Are samples set aside according to a retain sample policy?	Yes The retains are kept at outside cold storage.
4.3.4	Are inspection reports reviewed before products are released for sale?	Yes
4.3.5	Are inspection reports reviewed before products are released for sale?	Yes
4.3.6	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant has an inspection process to determine if the product meets customer and internal specifications. The product is sampled, tested in-house and/or at an outside laboratory. Results are reviewed prior to release. The plant keeps retain samples at outside cold storage.
		Facility's Response to Auditor's Observations

Section 4.4 Control of Non conforming Materials		
	AUDIT ITEM	OBSERVATION
4.4.1	Does the facility have Hold procedures define what circumstances lead to a "HOLD" decision and the scope/amount of product to be held?	Yes. A brief description follows: All product is processed and placed on hold. The product which does not conform to specifications will remain on hold until the Greenwood Associates technical group determines what the issues are, if further testing is required, or if the product can re-enter sales.
4.4.2	Are food safety related ("Holds") handled with sufficient care and scrutiny?	Yes
4.4.3	Do product non conformance procedures apply to raw materials work in progress AND finished products (when	Yes

	applicable)?	
4.4.4	Do procedures exist to request permission from customers before release of non conforming products?	Yes If the product is non-conforming on a non-critical attribute, the sales team may contact the customer, with a copy of the COA showing the out of specification parameter, and see if the customer is willing to take the product based the batch attributes.
4.4.5	Does the facility regularly inventory products with a "HOLD" status?	Yes
4.4.6	Is the disposition of product for release or destruction done only by employees who are authorized to perform this function?	Yes
4.4.7	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant has a documented procedure to hold non-conforming goods. Greenwood Associates technical staff reviews documentation from all product produced and keeps on hold any non-conforming product. The technical staff make the decision on disposal or sale of the product. The customers are asked if product which is non-conforming to a non-critical specification may be sent.
		Facility's Response to Auditor's Observations

Section 4.5 Good Laboratory Practices		
	AUDIT ITEM	OBSERVATION
4.5.1	Is physical analytical and/or microbiological testing performed in house at this facility?	Yes
4.5.2	Are effective controls in place that prevent facility in house laboratories from becoming a source of contamination to production areas and products?	Yes The plant does not perform microbiology testing. Only pH, Brix and other chemistry testing is done. All glassware remains in the laboratory.
4.5.3	Is physical microbiological or analytical testing performed by contract laboratories?	Yes The plant outsources finished product testing to Silliker, Inc.
4.5.4	If contract laboratories are used does the facility verify these laboratories also conduct self validation procedures?	Yes Copies of proficiency testing are obtained by the plant.
4.5.5	Do in house laboratory procedures follow recognized and/or official methodology for example FDA AOAC NOM BAM USDA or customers' methods etc?	Yes
4.5.6	Does the facility determine the receiving	N / A There is no exportation of product at this time.

	country's product testing requirements (if products are manufactured for export)?	
4.5.7	Does the facility periodically confirm that 1) test methods are accurate at the stated limit of detection 2) quantitative methods are accurate throughout the desired range and 3) established procedures are followed?	No. Additional details follow: The plant uses meters to test product, e.g. Brix and pH. Readings are good throughout the register of the unit and the units are calibrated.
4.5.8	Does the facility verify in house analysts are capable of performing laboratory procedures with accuracy and precision?	No The plant has neither external nor internal check sample programs. Additionally, they do not test knowledge of the analysts.
4.5.9	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has an in-house laboratory for pH and Brix and uses an external laboratory. The plant testing is done using meters which are calibrated throughout their range. The plant laboratory does not perform microbiology testing. The proficiency testing of the outside laboratory is obtained. The plant does not test the knowledge of in house analysts.
		Facility's Response to Auditor's Observations

Section 4.6 Document Control and Record Retention		
	AUDIT ITEM	OBSERVATION
4.6.1	Does the facility have a proper document control system to manage food safety and quality related data/records?	Yes The program covers retention of records. The program does not cover electronically held data.
4.6.2	Does the facility control access to electronic records?	Yes Access is controlled with pass codes. Storage times and retention are unknown.
4.6.3	Does the facility follow proper procedures when making corrections to records?	No. Additional details follow: Cross-outs were seen on records. Proper correction techniques were not covered in the document control policy.
4.6.4	Are food safety and quality related records signed and dated by the reviewer indicating records were verified?	Yes
4.6.5	Do procedures exist to notify management when discrepancies are discovered during the record review process?	Yes A member of the Greenwood Associates management staff is reviewing the daily records.
4.6.6	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		

	The plant has a document and record control policy which covers the retention of records. The policy did not cover corrections to documents, electronically held documents, nor did it cover policy creation, storage, or obseletion. Write overs were seen on records. Reviewers from management did acknowledge the review of records.
	Facility's Response to Auditor's Observations

Section 4.7 Corrective and Preventive Action		
	AUDIT ITEM	OBSERVATION
4.7.1	Does the facility have a documented approach or program for corrective and preventive actions when problems occur?	Yes An example of the corrective action program was reviewed in detail. On 11.18.10 environmental swabbing and air exposure testing was performed at Juice Tyme for Greenwood Associates. Corrective actions required as a result of the testing performed: Corrective action 1 - appropriate staff have been trained for prolonged air exposure/contamination. Corrective action 2 - Pail filling hose sanitation improvement will be done by replacing the current pail filling hose and then daily C.I.P. cleaning. Corrective action 3 - effective December 2010 Juice Tyme will conduct monthly microbiological testing of process equipment, environment, food contact packaging, raw ingredients and finished product for Greenwood Associates.
4.7.2	Does the facility proactively collect and analyze data that would help it prevent future product failures?	Yes
4.7.3	Summary and Comments	
	SECTION JUDGMENT:	Fully Meets
	SECTION SUMMARY:	Greenwood Associates has a corrective action program. The program is documented and an example was shown. The plant does seek opportunities and analyze data to avoid system failures.
		Facility's Response to Auditor's Observations

Section 4.8 Continuous Improvement		
	AUDIT ITEM	OBSERVATION
4.8.1	** Does the facility have a continuous improvement program?	Yes The group stated they are updating their database so that customers requiring specific testing are identified and only those lots meeting their testing needs will be chosen. They have already included the names of labs where testing is completed into our purchase orders to identify locations for customers. They also have instituted a blending policy that includes the specifications being printed with all blends. Also, Juice Tyme has instituted a new policy requiring the completion of a pre-blend and post-blend checklist regarding all product brought into the blending area. They have also updated our database so that nothing can ship without a COA already in the system without management approval (bills of lading won't print).
4.8.2	Summary and Comments	
	SECTION JUDGMENT:	Fully Meets
	SECTION SUMMARY:	The plant has a continuous excellence program which includes a number of initiatives. Initiatives include business functions and quality. One example also revealed customer

	satisfaction.
	Facility's Response to Auditor's Observations

Section 4.9 Customer / Consumer Communication		
	AUDIT ITEM	OBSERVATION
4.9.1	Does the facility have customer/consumer communication procedures for handling complaints suggestions and inquiries?	Yes
4.9.2	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		Customer feedback is given directly to the Sales Manager at Greenwood Associates. The Sales Manager exchanges emails with the technical staff to determine the cause of any issues. The feedback is given within hours to the customer.
		Facility's Response to Auditor's Observations

Section 4.10 Internal Self auditing		
	AUDIT ITEM	OBSERVATION
4.10.1	Does the facility conduct internal self audits?	Yes
4.10.2	Does the facility designate AND train specific individuals to manage the internal self audit program?	Yes
4.10.3	Are issues uncovered through internal audits PROMPTLY resolved?	No. Additional details follow: Issues are identified as corrected, but no follow up is done to ensure the corrective actions are complete and effective.
4.10.4	Does the facility management team periodically review results and corrective actions resulting from the internal audit program?	No. Additional details follow: The management team does not internally review the audits as the QA Manager is the lead on most audits.
4.10.5	Summary and Comments	
SECTION JUDGMENT:		Substantially Meets
SECTION SUMMARY:		The plant has routing audits which are conducted by the QA Manager. The audits include GMP, housekeeping, and security. The audits do not include reviews of documentation provided by operators. The audits are not reviewed by the management of the plant since a member of management is performing the audits. The corrections are documented, but no follow up is done to see the corrections are complete and effective.
		Facility's Response to Auditor's Observations

5.0 REGULATORY CONSIDERATIONS		
Section 5.1 Label Control		

AUDIT ITEM		OBSERVATION
5.1.1	Has the facility implemented a label approval process?	Yes
5.1.2	Does the facility verify labels comply with regulatory requirements?	Yes
5.1.3	Does the facility obtain and verify nutritional information for labels?	N / A The plant does not provide nutritional information on the label.
5.1.4	** Did packaging and labels applied during the Assessment match the product and its formulation?	Yes
5.1.5	Do labels include appropriate health/processing or product claims?	Yes. A brief description follows: Kosher claims are applied as appropriate.
5.1.6	Are procedures followed during changeover to ensure removal of incorrect labels from equipment the line and surrounding areas?	Yes Only the labels needed for a batch are printed. At the end, any remaining labels are discarded.
5.1.7	Are documented procedures in place to prevent inadvertent intermingling of labels or other printed materials?	N / A
5.1.8	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant manufactures labels for each batch. At the end of the batch labels are discarded. The labels are printed with the identity of the contents, but not nutritional information as the product is sold only to further processors. The plant does have some products which are claimed as Kosher, and are properly marked.
		Facility's Response to Auditor's Observations

Section 5.2 Regulatory & Industry Compliance		
AUDIT ITEM		OBSERVATION
5.2.1	Does the facility use the services of a Process Authority?	N / A The plant does not heat treat products.
5.2.2	Have all documented non compliance issues noted by regulatory authorities during the previous twelve months been resolved?	Yes The documented issues from an FDA audit in September at the JuiceTyme facility have been resolved. The audit was not directed at Greenwood products.
5.2.3	Summary and Comments	
SECTION JUDGMENT:		Fully Meets
SECTION SUMMARY:		The plant does not heat treat products. The documented issues from an FDA audit in September at the JuiceTyme facility have been resolved. The audit was not directed at Greenwood products.

	Facility's Response to Auditor's Observations

Section 5.3 Management of the Regulatory Inspection Process

AUDIT ITEM	OBSERVATION
5.3.1 Does the facility have pre established procedures for handling regulatory inspections whether planned or unscheduled?	Yes Audit Procedures are mapped out to state company officials will greet the auditor and conduct the meeting in a meeting room or office. During the audit all records pertaining to the audit will be made available to the auditor. If copies are needed to be made, the appropriate company official will make copies. All copies taken by the auditor will be in duplicate by the Director of Technical Service. For any findings requiring corrective actions, there will be a thorough discussion between the auditor and the company officials to ensure there is a clear understanding of action items found. After or during the audit the immediate corrective action is implemented and a reply letter will be drafted to include the corrective and preventative actions with time frames.
5.3.2 Does the facility notify customers if a regulatory inspection determines the product to be out of compliance?	Yes
5.3.3 Do regulatory inspection procedures require duplicate samples be collected and inventory be held when samples are taken by the regulator?	Yes
5.3.4 Does the facility notify customers when a regulator evaluates that customer's product?	Yes
5.3.5 Does the facility notify customers when a regulator is given copies of written documents pertaining to its products?	Yes
5.3.6 Summary and Comments	

SECTION JUDGMENT: Fully Meets

SECTION SUMMARY: Audit Procedures are mapped out to state company officials will greet the auditor and conduct the meeting in a meeting room or office. During the audit all records pertaining to the audit will be made available to the auditor. If copies are needed to be made, the appropriate company official will make copies. All copies taken by the auditor will be in duplicate by the Director of Technical Service. For any findings requiring corrective actions, there will be a thorough discussion between the auditor and the company officials to ensure there is a clear understanding of action items found. After or during the audit the immediate corrective action is implemented and a reply letter will be drafted to include the corrective and preventative actions with time frames. Customers are notified if an inspection determines an out-of-compliance product. Customers are notified if a regulator evaluates a customers product or when a regulator is given copies of written documents pertaining to its product.

	Facility's Response to Auditor's Observations