

Clear Form PAGE 1 OF 4



### MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES BUREAU OF ENVIRONMENTAL HEALTH SERVICES P.O. BOX 570, JEFFERSON CITY, MO 65102-0570 (866) 628-9891 (573) 751-6095 MANUFACTURED FOOD FIRM INSPECTION REPORT

FDA CONTRACT INSPECTION This is an FDA contract inspection RISK CATEGORY

High

Inspection completed under authority provided to the Missouri Department of Health and Senior Services (DHSS) under 196.055 RSMo. Missouri Law prohibits the refusal of free access to DHSS, including entry, inspection, record and sample collection. Missouri Law prohibits DHSS from prescribing regulations that are more stringent than federal regulations or from disclosing industry trade secrets entitled to protection.

FEI       FIRM NAME         3010127986       Two Men and a Garden LLC         PHYSICAL ADDRESS       CITY         4564 N Square Dr       High Ridge         MAILING ADDRESS       CITY         Same       State         Same       Mo         FIRM POINT OF CONTACT (FIRST/MI/LAST/TITLE)       CONTACT EMAIL ADDRESS (OR FAX)         Joel P Austin owner       Joel@ twomenandagarden.com         MOST RESPONSIBLE PERSON AT THIS LOCATION (FIRST/MI/LAST/TITLE)       CONTACT PHONE NUMBER         Joel P Austin owner       (314) 277-4229         PROCESS TYPES       HOURS/DAYS/SEASONS OF OPERATION         Acidified       M-F 8-4	FIRM DATA								
PHYSICAL ADDRESS     CITY     STATE     ZIP       4564 N Square Dr     High Ridge     Mo     63049       MAILING ADDRESS     CITY     STATE     ZIP       Same     Same     Mo     63049       FIRM POINT OF CONTACT (FIRST/MI/LAST/TITLE)     CONTACT EMAIL ADDRESS (OR FAX)     Joel @ twomenandagarden.com       Joel P Austin owner     Joel @ twomenandagarden.com        Most RESPONSIBLE PERSON AT THIS LOCATION (FIRST/MI/LAST/TITLE)     CONTACT PHONE NUMBER        Joel P Austin owner     (314) 277-4229         PROCESS TYPES     HOURS/DAYS/SEASONS OF OPERATION     M-F 8-4									
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PRODUCT AND PROCESSING DETAILS		AILS							
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WATER SUPPLY WATER SAMPLE WASTEWATER						\\/\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	D		
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INSPECTION DATA									
Inspection DateInspection DateInspection Tree11/9/2010 amRoutineGMP/Limited Scope PC									
					DATE OF PREVIOUS INSPECTION PREVIOUS INSPECTION CLASSIFICATION				
John P Austin owner 12/11/18 VAI									
ADDITIONAL PEOPLE PRESENT (NAME & TITLE OR AGENCY) SIGNIFICANT CHANGES SINCE LAST INSPECTION					SIGNIFICANT CHANGES SINCE LAST INSPECTION				
					Address only				
INSPECTION NOTICE PROVIDED LOT CODING AND TRACEABILITY RECALLS COMPLAINTS									
No Reviewed None See Comments			Revie	wed		See Comments		nts	
	RECALL DETAILS								
None. Had a mock recall recently. July was last. Addressed situation. Complaint logs kept	None. Had a mock recall recently.				July was last. Addressed situation. Complaint logs kept				
	PROCESSES REVIEWED/OBSERVED			things of qualit				ATION STATUS	
No process of canning. Observed labeling and packaging at time of audit.	No process of carming. C	bserved	labelli	ig and packaging a	t time of audit.			Current	
FDA REGISTRATION REVIEW							Γ	FDA REGISTR	ATION REVIEW
No Inaccuracies Noted								No Inaccu	racies Noted
ANIMAL FOOD BYPRODUCTS							F	ANIMAL FOO	D BYPRODUCTS
No								No	



# MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES BUREAU OF ENVIRONMENTAL HEALTH SERVICES P.O. BOX 570, JEFFERSON CITY, MO 65102-0570 (866) 628-9891 (573) 751-6095 MANUFACTURED FOOD FIRM INSPECTION REPORT

PAGE 2 OF 4

INSPECTION DATE
4/0/00

11/9/20

FEI 3010127986

### FIRM NAME Two Men and a Garden LLC

RECONCILIATION EXAM Celery seed whole 16 oz. 6 each.#1158. Verified. SAMPLES None PRA GUIDANCE DOCUMENTS PROVIDED IS FIRM COVERED BY 21 CFR 121? None POLLOW-UP DATE None POLLOW-UP DATE NONE NALASSING SUBJECTOR FOLLOW-UP/CLOSEOUT COMMENTS NESPECTOR FOLLO	CLOSEOUT					
SAMPLES None PDA GUIDANCE DOCUMENTS PROVIDED IS FIRM COVERED BY 21 CFR 121? None POLLOW-UP DATE None POLLOW-UP DATE None MANAGEMENT'S RESPONSE TO INSPECTION FINDINGS Willing to fix above items. INSPECTOR FOLLOW-UP/CLOSEOUT COMMENTS INSPECTOR FOLLOW-UP/CLOSEOUT COMMENTS INSPECTOR FOLLOW-UP/CLOSEOUT COMMENTS INSPECTOR ROLLOW-UP/CLOSEOUT COMMENTS INSPECTOR RESPONSE COMME						
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Emailed to Joel P Austin owner       11/9/20	FIRM REPRESENTATIVE SIGNATURE					



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PAGE 3 OF 4

INSPECTION DATE

11/9/20

FEI 3010127986

FIRM NAME Two Men and a Garden LLC

The checklist below represents the typical scope of coverage of a Limited-Scope Preventive Control/Good Manufacturing Practice Inspection. Based on an inspection this day, the items marked "OUT" below identify noncompliance in operations or facilities. Additional details regarding these findings are provided under the Inspection Results header beginning on page 4. In=In Compliance Out=Not In Compliance (explained on additional pages) N/O=Not Observed N/A=Not Applicable

21 CFR 117			
Fraining § 117.4 & 117.100 compliance status:	IN	Processes and Controls § 117.80 compliance status:	OU
Management responsibilities - qualified individuals		Equipment and utensils - design and maintenance	
Training of employees and records		Plant operations - precautions	
Personnel § 117.10 compliance status:	IN	Appropriate quality control operations	
Disease control		Plant sanitation competently supervised	
Personal cleanliness		Adulterated foods rejected	
Hand washing		Raw materials controls - cleaning - water quality	
Jewelry		Raw materials controls - treatment for microorganisms	
Glove use		Raw materials controls - natural toxins	
Hair restraints		Raw materials/ingredients/rework - filth and contamination	n
Personal belongings		Identification and storage of rework	
Eating/drinking/gum/tobacco		Raw materials - freezing and thawing	
Precautions against other foreign substances		Raw materials - allergen identification	
Plants and Grounds § 117.20 compliance status:	IN	Manufacturing, processing, packing, holding - controls	
Grounds		Process control measures	
Plant construction and design		Process control - foreign objects	
Sanitary Operations §117.35 compliance status:	Adulterated food disposition		
Plant maintenance and sanitation	IN	Warehousing and Distribution § 117.93 compliance status:	N/A
Cleaning and sanitizing substances- safe and adequate		Food storage and transportation protection	1 1/7
Toxic chemicals - identified, held, stored		Animal Food By-Products § 117.95 compliance status:	N/A
Pest control		Human food by-products	
Sanitation of food contact surfaces - frequency			IN
Sanitation of non-food contact surfaces - frequency		Food Safety Plan (FSP) § 117.126 compliance status:	IIN
Storage and handling of cleaned equipment		Written FSP in place	
	OUT	Written FSP prepared by PCQI	
Sanitary Facilities and Controls §117.37 compliance status:	OUT	Hazard analysis in FSP	
Water supply: approved source, construction and operation	1	Preventive controls in FSP	
Drinking water quality standards met		Supply-chain program in FSP	
Plumbing size and design		Recall plan in FSP	
Backflow prevention Wastewater disposal: construction, operation and mainter	2220	Monitoring the implementation of preventive controls in FS	SP
Toilet facilities	lance	Corrective actions in FSP	
Handwashing facilities		Verification procedures in FSP	
Rubbish and offal disposal		Preventive Controls § 117.135 compliance status:	N/A
·		Process controls	
Equipment and Utensils § 117.40 compliance status:	IN	Food allergen controls	
Equipment and utensils – general design and maintenance		Sanitation controls	
Hoses and pumps properly designed and constructed		Supply-chain controls	
Indicating thermometers present		Other controls	
Instruments (pH, Aw, temp, etc.) calibrated and adequate		Modified Requirements § 117.201 & .206 compliance status:	IN
Compressed air/gas prevents contamination		Qualified Facility attestation	
		Warehouse temperature controls	
ADDITIONAL REGULATIONS			
21 CFR 101 Labeling compliance status:	IN	21 CFR 120 Juice HACCP compliance status:	N/A
			N/A



# MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES BUREAU OF ENVIRONMENTAL HEALTH SERVICES P.O. BOX 570, JEFFERSON CITY, MO 65102-0570 (866) 628-9891 (573) 751-6095 MANUFACTURED FOOD FIRM INSPECTION REPORT

PAGE 4 OF 4

INSPECTION DATE

11/9/20 FEI

3010127986

FIRM NAME Two Men and a Garden LLC

<b>INSPECTION RE</b>	SULTS
RULE REFERENCE	ADVERSE CONDITIONS FOLLOW UP DATE
117.37(e)	Hand washing sink was out of paper towels and soap.
117.80(c)(1)	Some food grade tubs that are used for liquid has cracks and could potentially cause a hazard. Discard and get new tubs.
	potentially cause a nazaru. Discaru and get new tubs.
COMMENTS/DISCUS	SION ITEMS
Several sinks	observed and it was unclear if there were for hand washing only or for break room
employees. D	Discussed making a firm decision on the use and labeling it.
1	