



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

Print	Clear Form
PAGE 1 OF 4	
FDA CONTRACT INSPECTION This is an FDA contract inspection	
RISK CATEGORY Medium	

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.

FIRM DATA				
FEI 3012143461		FIRM NAME Park Avenue Coffee Roasters		
PHYSICAL ADDRESS 5105 Columbia St		CITY St. Louis	STATE Mo	ZIP 63139
MAILING ADDRESS Same		CITY	STATE	ZIP
FIRM POINT OF CONTACT (FIRST/MI/LAST/TITLE) Dale A Schote. President		CONTACT EMAIL ADDRESS (OR FAX) Dale@parkavenuecoffee.com		
MOST RESPONSIBLE PERSON AT THIS LOCATION (FIRST/MI/LAST/TITLE) Same		CONTACT PHONE NUMBER (314) 265-5000		
PROCESS TYPES Beverage		HOURS/DAYS/SEASONS OF OPERATION M-F 8-5		
FIRM SIZE 5	% INTERSTATE 60%	% WHOLESALE 100	NO. OF EMPLOYEES 5	
PRODUCT AND PROCESSING DETAILS Coffee roasting				
WATER SUPPLY Public		WATER SAMPLE None	WASTEWATER Public	
INSPECTION DATA				
INSPECTION DATE 12/3/20	TIME IN 10:30 am	REASON FOR INSPECTION Routine	INSPECTION TYPE GMP/Limited Scope PC	
CREDENTIALS SHOWN TO (FIRST/MI/LAST/TITLE) Dale A Schote. President		DATE OF PREVIOUS INSPECTION 10/18/17	PREVIOUS INSPECTION CLASSIFICATION VAI	
ADDITIONAL PEOPLE PRESENT (NAME & TITLE OR AGENCY) None		SIGNIFICANT CHANGES SINCE LAST INSPECTION None		
INSPECTION NOTICE PROVIDED No	LOT CODING AND TRACEABILITY Reviewed	RECALLS None	COMPLAINTS See Comments	
RECALL DETAILS None		COMPLAINT DETAILS Complaint logs maintained.		
PROCESSES REVIEWED/OBSERVED No processing at time due to roaster being out due to COVID.			FDA REGISTRATION STATUS Current	
			FDA REGISTRATION REVIEW No Inaccuracies Noted	
			ANIMAL FOOD BYPRODUCTS No	



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12/3/20
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FIRM NAME

Park Avenue Coffee Roasters

CLOSEOUT

RECONCILIATION EXAM

Green coffee Alma del Cafe Excelso 10.00. 70 kg bags DO0061783.

SAMPLES

None

FDA GUIDANCE DOCUMENTS PROVIDED

Yes

IS FIRM COVERED BY 21 CFR 121?

No

REFUSALS

None

INSPECTION CLASSIFICATION

NAI

FOLLOW-UP

None

FOLLOW-UP DATE

MANAGEMENT'S RESPONSE TO INSPECTION FINDINGS

NA

INSPECTOR FOLLOW-UP/CLOSEOUT COMMENTS

**Mock recalls done two times a year.
 Firm does a nice job on keeping all records in one large binder.
 Firm has moved up to a 5. All areas were checked and in compliance. Food defense plan was added this year.**

INSPECTOR SIGNATURE

DATE COMPLETED

12/3/20

INSPECTOR NAME

Natasha Sullivan

TIME OUT

12:45

INSPECTOR EMAIL

Natasha.sullivan@health.mo.gov

INSPECTOR TELEPHONE

(314) 406-5040

You are reminded to adhere to the Food, Drug and Cosmetic Act; failure to do so can result in seizure, injunction or prosecution.

FIRM REPRESENTATIVE SIGNATURE

Emailed to Dale A Schote. President

DATE

12/3/20

FIRM REPRESENTATIVE NAME/TITLE

Dale A Schote. President



INSPECTION DATE
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Park Avenue Coffee Roasters

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	
Training § 117.4 & 117.100 compliance status: IN	Processes and Controls § 117.80 compliance status: IN
Management responsibilities - qualified individuals Training of employees and records	Equipment and utensils - design and maintenance Plant operations - precautions Appropriate quality control operations Plant sanitation competently supervised Adulterated foods rejected
Personnel § 117.10 compliance status: IN	Raw materials controls - cleaning - water quality Raw materials controls - treatment for microorganisms Raw materials controls - natural toxins Raw materials/ingredients/rework - filth and contamination Identification and storage of rework Raw materials - freezing and thawing Raw materials - allergen identification
Disease control Personal cleanliness Hand washing Jewelry Glove use Hair restraints Personal belongings Eating/drinking/gum/tobacco Precautions against other foreign substances	Manufacturing, processing, packing, holding - controls Process control measures Process control - foreign objects Adulterated food disposition
Plants and Grounds § 117.20 compliance status: IN	Warehousing and Distribution § 117.93 compliance status: IN
Grounds Plant construction and design	Food storage and transportation protection
Sanitary Operations §117.35 compliance status: IN	Animal Food By-Products § 117.95 compliance status: N/A
Plant maintenance and sanitation Cleaning and sanitizing substances- safe and adequate Toxic chemicals - identified, held, stored Pest control Sanitation of food contact surfaces - frequency Sanitation of non-food contact surfaces - frequency Storage and handling of cleaned equipment	Human food by-products
Sanitary Facilities and Controls §117.37 compliance status: IN	Food Safety Plan (FSP) § 117.126 compliance status: IN
Water supply: approved source, construction and operation Drinking water quality standards met Plumbing size and design Backflow prevention Wastewater disposal: construction, operation and maintenance Toilet facilities Handwashing facilities Rubbish and offal disposal	Written FSP in place Written FSP prepared by PCQI Hazard analysis in FSP Preventive controls in FSP Supply-chain program in FSP Recall plan in FSP Monitoring the implementation of preventive controls in FSP Corrective actions in FSP Verification procedures in FSP
Equipment and Utensils § 117.40 compliance status: IN	Preventive Controls § 117.135 compliance status: N/A
Equipment and utensils – general design and maintenance Hoses and pumps properly designed and constructed Indicating thermometers present Instruments (pH, Aw, temp, etc.) calibrated and adequate Compressed air/gas prevents contamination	Process controls Food allergen controls Sanitation controls Supply-chain controls Other controls
	Modified Requirements § 117.201 & .206 compliance status: N/A
	Qualified Facility attestation Warehouse temperature controls
ADDITIONAL REGULATIONS	
21 CFR 101 Labeling compliance status: IN	21 CFR 120 Juice HACCP compliance status: N/A
21 CFR 114 Acidified Foods compliance status: N/A	21 CFR 123 Seafood HACCP compliance status: N/A



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INSPECTION RESULTS

RULE REFERENCE	ADVERSE CONDITIONS	FOLLOW UP DATE

COMMENTS/DISCUSSION ITEMS
 Discussed putting a self closing mechanism on the employee restroom door.
 Discussed keeping area that non food items are stored, clean and free of obstruction.