

Good Manufacturing Practice (GMP) Inspection Report

Inspector Contact Information

Sander Robinson
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Facility Name: MODEST COFFEE, INC.

Facility #: 3005
 245 W Roosevelt Road Building 2 Suite 15
 West Chicago, Illinois 60185
 7085958775
FEIN:
Establishment Size: \$100,000 - \$499,999

Mailing Address

245 W Roosevelt Rd., Bldg. 2 STE 15
 West Chicago, IL 60185
 orders@modest-coffee.com

Person Interviewed	Jennifer Contaldo	Person Interviewed Title:	Co-Owner
Person Interviewed Date	10/24/2018	Person Interviewed Telephone	708-595-8775
Person Interviewed Email	orders@modest-coffee.com	FDA Contract Number:	
Sanitizer or Caustic Solution:	Chlorine-based: Equipment; Quat-based: Surfaces	Refrigerator Storage Temperature:	
Frozen Storage Temperature:		Sample Numbers if applicable:	
Related Firms/Sources:			

IN = In Compliance, OUT = Out of Compliance, N/A = Not Applicable, C = Corrected On Site, R = Repeat Violation

Qualifications of individuals who manufacture, process, pack, or hold food

Applicability

01 Management ensuring qualifications	IN
02 Agent in charge ensuring qualifications	IN

Qualifications of individuals who manufacture, process, pack, or hold food

03 Requirements of Qualified Individual	IN
04 Training	IN

Additional qualifications of supervisory personnel

05 Ensuring Compliance	IN
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Records

06 Records	IN
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Personnel

Disease Control

07 Employees with illness, lesions, contamination source	IN
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Cleanliness

08 Suitable outer garments	IN
09 Personal Cleanliness	IN
10 Not washed/ Sanitized when appropriate	IN
11 Unsecured jewelry / Removal/covering of Hand jewelry	IN
12 Glove Condition	IN
13 Failure to wear Hair restraints	IN
14 Storage of personal items	IN
15 Personal food/drink/tobacco	OUT
16 Precautions against contamination -- micro, foreign in substances	IN

Plants and Grounds

Grounds

17 Harborage areas	IN
18 Roads/yards/parking lots	IN
19 Draining	IN
20 Waste Disposal	IN
21 Neighboring Property not under Operator Control	IN

Plant Construction and Design

22 Sufficient Space	IN
23 Contamination with microorganisms, chemicals, filth, etc.	IN
24 Outdoor Bulk Vessels	IN
25 Controlling Pests around Bulk Vessels	IN
26 Use of protective coverings	IN
27 Checking for pests and pest infestations	IN
28 Skimming Fermentation Vessels	IN
29 Floors, walls, ceilings, drips, condensate and spacing of equipment	IN
30 Adequate/Safety Lighting	IN

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31	Adequate ventilation/operation of Fans and air blowing equipment	IN
32	Screening	IN
Sanitary Operations		
General Maintenance		
33	Buildings/ Sanitary	IN
Substance used in cleaning and sanitizing:storage of toxic materials		
34	Safe and Adequate for use	IN
35	Unacceptable toxic compounds	IN
36	Storage Requirements	IN
Pest control		
37	Lack of effective pest exclusion	IN
Sanitation of food contact surfaces		
38	Failure to clean-Food contact items	IN
39	Low moisture food requirements	IN
40	Before use and after interruption	IN
41	Single service articles	IN
42	Failure to clean- non-Food contact services	IN
Storage and Handling of Cleaned Portable equipment		
43	Storage of cleaned portable equipment (S)	IN
Sanitary Facilities and Controls		
Water Supply		
44	Safe and Adequate water use	IN
Plumbing		
45	Sufficient Quantities of Water	IN
46	Convey Sewage	IN
47	As a source of contamination	IN
48	Drainage	IN
49	Waste Water- Backflow and Cross-connection	IN
Sewage Disposal		
50	Sewage Disposal	IN
Toilet Facilities		
51	Toilet Facilities	IN
Hand washing facilities		
52	Hand washing facilities	IN
Rubbish and offal disposal		
53	Rubbish and offal disposal	OUT
Equipment and Utensils		
Design and Workmanship of Utensils and Equipment		
54	Materials and Workmanship	IN
55	Precluding Contaminants	IN
56	Installation and Maintenance of Equipment	IN
57	Food contact- corrosion resistant	IN
58	Food Contact- surfaces withstanding use	IN
59	Food Contact- unlawful indirect additives	IN
Seams on food contact surfaces		
60	Seams on food contact surfaces	IN
Design and construction of non-food contact surfaces		
61	Non-food contact equipment in processing area	IN
Design and Construction of holding, conveying, and manufacturing systems		
62	Holding, conveying, mgf systems-design and construction	IN
Temperature measuring devices		
63	Lack of thermometer	IN
Instrument accuracy and adequacy		
64	Q.C. instrument accuracy and adequacy	IN
Compressed air/gases		
65	Compressed air/gases	IN
Processes and Controls		
General		
66	Adequate Sanitation Principles	IN
67	Quality Control	IN
68	Supervisory competence	IN
69	Reasonable Precautions	IN
70	Testing	IN
71	Reject and Rework	IN
Raw Materials and Ingredients		
72	Handling of Raw Materials	OUT, (*)

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73	Pasteurization or other adequate treatment	IN
74	Aflatoxin and other natural toxins	IN
75	Safety assurance-pests/extraneous materials	IN
76	Holding in bulk or suitable containers	IN
77	Frozen and Thawed raw foods	IN
78	Receipt/ Storage- liquid and dry raw materials	IN
79	Food Allergens	IN
	Manufacturing Operations	
80	Maintenance of Equipment, utensils, and finished food packaging	IN
81	Manufacturing conditions	IN
82	Holding foods-refrigerate /freeze/ heat	IN
83	Preventive control measures	IN
84	Work-in-progress	IN
85	Contamination by raw materials, refuse, other ingredients	IN
86	Equipment, containers, utensils	IN
87	Metal/ extraneous materials	IN
88	Proper Disposal of adulterated product	IN
89	Mechanical manufacturing control	IN
90	Heat blanching concerns	IN
91	Batters, breading, gravies, sauces, etc.	IN
92	Filling, assembling, packing controls	IN
93	Water activity controls	IN
94	Proper pH controls	IN
95	Ice manufacturing	IN
	Warehousing and Distribution	
	Storage/ Transportation	
96	Storage/Transportation of finished good	IN
	Holding and Distribution of Human Food By-products for use as Animal Food	
	Protection against Contamination	
97	Containers and Equipment	IN
98	Protection from Contamination Sources	IN
99	Identification	IN
	Labeling	
100	Labeling	IN
	Shipping Containers	
101	Examination of Shipping Containers	IN
	Defect Action Levels	
	Compliance	
102	Defects not reduced to lowest level	IN
	Blending adulterated food	
103	Blending	IN
	Records subject to the requirement of this subpart F	
104	Records subject to subpart F	IN
	General requirements applying to records	
105	Original records	IN
106	Values and Observations	IN
107	Accuracy	IN
108	Date of Creation	IN
109	Detail	IN
110	Inclusion of proper information	IN
111	Exemptions from Part 11	IN
	Additional requirements applying to the food safety plan	
112	Food Safety Plan requirements	N/A
	Requirements for record retention	
113	Timeline of Retention	IN
114	General Adequacy Timeline for retention	IN
115	Offsite storage	IN
116	Facility closing	IN
117	Availability	IN
	Use of existing records	
118	Disclosure requirements	IN
119	Duplication	IN
	Requirements for official review	
120	Sets of Records	IN
	Special Requirements applicable to a written assurance	

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121	Requirements of all Written Assurances	IN
122	Requirements of Written Assurances Under 117.136(a)(2), (3), (4)	IN

Observations and Corrective Actions				
Violations cited in this report must be corrected within the inspector's specified timeframes				
Priority Level	Item Number	Violation of Code	Comment	Correct By Date
	15	21 CFR 117.10 (b)(8)	Personal food items were found stored in the processing area, which include ice cream in a freezer chest and beer in a refrigerator.	
	53	21 CFR 117.37(f)	Small trash cans in processing area do not have lids.	
	72	21 CFR 117.80 (b)(1)	Bags of raw coffee beans were left open. Corrected on site.	
	Total	3		

Inspection Published Comment:
A routine state inspection of Modest Coffee, Inc., located at 245 W. Roosevelt Rd., Bldg. 2, Ste. 15, West Chicago (DuPage County), was conducted on 10/24/18 by Sander Robinson (EHS II).

Finished products in this ambient and refrigerated raw coffee bean processing and warehousing facility include roasted whole bean and ground coffee, as described in previous inspections. Raw beans are single-sourced until that particular lot is gone. Genuine Origin (warehouse, Harrisburg, PA) supplies the raw beans. Cold-brewed coffee is placed in 12 oz. glass bottles (12/case). Modest Coffee uses its own label. Batches are coded/tracked with a month/day/year roast date and lot numbers. Approximately 300 lb. (ave.) is produced per lot for whole bean and ground coffee.

This 1,200 sq. ft., 100% wholesale facility distributes products using a company van. 2 – 3 % of their business is out of state. Customers include a café out of Indiana Earlham University, Pepper Park Coffee (Lake Barrington), and Bubo Coffee (West Chicago). Grocery/restaurant customers include Casey's (Naperville), Standard Market (Naperville), Prisco (Aurora), Blue Goose (St. Charles), Pete's Fresh Market (Chicago area), Sunset Foods (north suburbs), and Caputo's (3 stores). The business does some online sales to individual customers. The owners also participate at farmer's markets (Deerfield, Naperville; Schaumburg). A mobile coffee cart is built for use at special events.

The owners have started constructing a retail selling area in the front end of the business. Retail materials are being stored in an adjacent room.


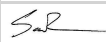
Two people are employed at the business (Co-owners Marcus and Jennifer Contaldo).

The notice of inspection and state credentials were presented to Ms. Contaldo. Ms. Contaldo also provided information for this report and accompanied the state inspector on a tour of the facility. The facility's registration with the FDA is current. After the inspection, updated FSMA PDF documents were e-mailed to management: Final Rule on Sanitary Transportation of Human and Animal Food, FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration, and Guidance for Industry: What You Need to Know About Registration of Food Facilities – Small Entity Compliance Guide. The state inspector did not include a Preventive Controls guidance document since the facility makes less than \$1M in gross annual sales. The owners will apply online for an exemption of the Hazard Analysis and Food Safety Plan requirements: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm>

Violations: 1) Small trash cans in processing area do not have lids. 2) Bags of raw coffee beans were left open. This violation was corrected on site. 3) Personal food items were found stored in the processing area, which include ice cream in a freezer chest and beer in a refrigerator. Ms. Contaldo stated items 1 and 3 would be corrected immediately.

No insect, avian or rodent activity was observed. A pest control company in this same business complex does routine pest control. The frequency of their visits is not known. Future pest maintenance records will be kept on site. More information regarding the pest service will be discussed during the next routine inspection. Chlorine and quat-based disinfectants are used to sanitize the facility equipment and countertops, respectively.

The facility uses a city water source.

Visit Date	Person Interviewed	Person Interviewed Signature	Sig. Date	Sanitarian	Sanitarian Signature	Sig. Date	Time In	Time Out
10/24/2018	Jennifer Contaldo		10/24/2018	Sander Robinson		10/24/2018	1:00 PM	2:30 PM