



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 1 OF
FDA CONTRACT INSPECTION
RISK CATEGORY

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	FIRM NAME		
PHYSICAL ADDRESS		CITY	STATE ZIP
MAILING ADDRESS		CITY	STATE ZIP
FIRM POINT OF CONTACT (FIRST/MI/LAST/TITLE)		CONTACT EMAIL ADDRESS (OR FAX)	
MOST RESPONSIBLE PERSON AT THIS LOCATION (FIRST/MI/LAST/TITLE)		CONTACT PHONE NUMBER	
PROCESS TYPES		HOURS/DAYS/SEASONS OF OPERATION	
FIRM SIZE	% INTERSTATE	% WHOLESALE	NO. OF EMPLOYEES
PRODUCT AND PROCESSING DETAILS			
WATER SUPPLY		WATER SAMPLE	WASTEWATER
INSPECTION DATA			
INSPECTION DATE	TIME IN	REASON FOR INSPECTION	INSPECTION TYPE
CREDENTIALS SHOWN TO (FIRST/MI/LAST/TITLE)		DATE OF PREVIOUS INSPECTION	PREVIOUS INSPECTION CLASSIFICATION
ADDITIONAL PEOPLE PRESENT (NAME & TITLE OR AGENCY)		SIGNIFICANT CHANGES SINCE LAST INSPECTION	
INSPECTION NOTICE PROVIDED	LOT CODING AND TRACEABILITY	RECALLS	COMPLAINTS
RECALL DETAILS		COMPLAINT DETAILS	
PROCESSES REVIEWED/OBSERVED			FDA REGISTRATION STATUS
			FDA REGISTRATION REVIEW
			ANIMAL FOOD BYPRODUCTS



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INSPECTION DATE

FEI

FIRM NAME

**CLOSEOUT**

RECONCILIATION EXAM

SAMPLES

FDA GUIDANCE DOCUMENTS PROVIDED

IS FIRM COVERED BY 21 CFR 121?

REFUSALS

INSPECTION CLASSIFICATION

FOLLOW-UP

FOLLOW-UP DATE

MANAGEMENT'S RESPONSE TO INSPECTION FINDINGS

INSPECTOR FOLLOW-UP/CLOSEOUT COMMENTS

INSPECTOR SIGNATURE

DATE COMPLETED

INSPECTOR NAME

TIME OUT

INSPECTOR EMAIL

INSPECTOR TELEPHONE

**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

DATE

FIRM REPRESENTATIVE NAME/TITLE



INSPECTION DATE

FEI

FIRM NAME

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**

<b>21 CFR 117</b>	
<b>Training § 117.4 &amp; 117.100 compliance status:</b>	<b>Processes and Controls § 117.80 compliance status:</b>
Management responsibilities - qualified individuals	Equipment and utensils - design and maintenance
Training of employees and records	Plant operations - precautions
<b>Personnel § 117.10 compliance status:</b>	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
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
<b>Plants and Grounds § 117.20 compliance status:</b>	Manufacturing, processing, packing, holding - controls
Grounds	Process control measures
Plant construction and design	Process control - foreign objects
<b>Sanitary Operations §117.35 compliance status:</b>	Adulterated food disposition
Plant maintenance and sanitation	<b>Warehousing and Distribution § 117.93 compliance status:</b>
Cleaning and sanitizing substances- safe and adequate	Food storage and transportation protection
Toxic chemicals - identified, held, stored	<b>Animal Food By-Products § 117.95 compliance status:</b>
Pest control	Human food by-products
Sanitation of food contact surfaces - frequency	<b>Food Safety Plan (FSP) § 117.126 compliance status:</b>
Sanitation of non-food contact surfaces - frequency	Written FSP in place
Storage and handling of cleaned equipment	Written FSP prepared by PCQI
<b>Sanitary Facilities and Controls §117.37 compliance status:</b>	Hazard analysis in FSP
Water supply: approved source, construction and operation	Preventive controls in FSP
Drinking water quality standards met	Supply-chain program in FSP
Plumbing size and design	Recall plan in FSP
Backflow prevention	Monitoring the implementation of preventive controls in FSP
Wastewater disposal: construction, operation and maintenance	Corrective actions in FSP
Toilet facilities	Verification procedures in FSP
Handwashing facilities	<b>Preventive Controls § 117.135 compliance status:</b>
Rubbish and offal disposal	Process controls
<b>Equipment and Utensils § 117.40 compliance status:</b>	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	<b>Modified Requirements § 117.201 &amp; .206 compliance status:</b>
Compressed air/gas prevents contamination	Qualified Facility attestation
	Warehouse temperature controls
<b>ADDITIONAL REGULATIONS</b>	
<b>21 CFR 101 Labeling compliance status:</b>	<b>21 CFR 120 Juice HACCP compliance status:</b>
<b>21 CFR 114 Acidified Foods compliance status:</b>	<b>21 CFR 123 Seafood HACCP compliance status:</b>



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**INSPECTION RESULTS**

RULE REFERENCE	ADVERSE CONDITIONS	FOLLOW UP DATE

COMMENTS/DISCUSSION ITEMS