

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	DATE(S) OF INSPECTION 12/16/2019-1/9/2020*
	FEI NUMBER 3004291002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Allen Tart, Senior Director of Operations

FIRM NAME J.M. Smucker Pet, LLC	STREET ADDRESS 6670 Low St
CITY, STATE, ZIP CODE, COUNTRY Bloomsburg, PA 17815-8613	TYPE ESTABLISHMENT INSPECTED Pet Food/LACF Processor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You did not identify and implement preventive controls to ensure that any hazards requiring a preventive control are significantly minimized or prevented.

This is a repeat observation from the previous inspection conducted on 03/15/2019.

Specifically, you did not implement Preventive Controls outlined in your Food Safety Plan for the Hazard: Nutrient Toxicity, which you identified as a hazard requiring a Process Control for your canned cat and dog foods you produced, which includes Special Kitty brand Mixed Grill Pate lot # 92630830B on 09/20/2019.

OBSERVATION 2

Your process controls did not include procedures, practices, and/or processes that ensure the control of parameters during operations to significantly minimize or prevent hazards.

This is a repeat observation from the previous inspection conducted on 03/15/2019.

Specifically, the previous inspection found that you use metal detectors on your dry product line to control the hazard of metal in your finished product. The validation you supplied documented that it was performed by (b) (4). However, your procedure for monitoring the operation of the metal detector (b) (4).

OBSERVATION 3

You did not verify that your preventive control(s) are consistently implemented and effective by other activities appropriate for verification of implementation and effectiveness.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sean D Duke, Investigator	 Sean D Duke Investigator	DATE ISSUED 1/9/2020

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This is a repeat observation from the previous inspection conducted on 03/15/2019.

Specifically, the previous inspection found that you perform (b) (4) [REDACTED]
[REDACTED] The records you provided during that inspection documented that the test result for the premix mixer was approximately (b) (4) standard deviations from the mean. (4)

***DATES OF INSPECTION**
12/16/2019(Mon), 12/17/2019(Tue), 12/18/2019(Wed), 1/09/2020(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sean D Duke, Investigator	 <small>Sean D Duke Investigator</small>	DATE ISSUED 1/9/2020

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."