

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768		DATE(S) OF INSPECTION 3/2/2026-3/5/2026 FEI NUMBER 3025523697	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Carlo [nm] Ferrario, Plant Manager			
FIRM NAME Farmina Pet Food USA LLC		STREET ADDRESS 248 Sands Rd	
CITY, STATE, ZIP CODE, COUNTRY Reidsville, NC 27320-6522		TYPE ESTABLISHMENT INSPECTED Pet Food Manufacturer	
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 evaluate each known or reasonably foreseeable hazard for each type of animal food you manufacture, process, pack or hold in your facility. Specifically, your Food Safety Plan for Dry Pet Food contains a written hazard analysis identified as Section 7, Ingredient Risk Assessment. This hazard analysis only contained a partial list of ingredients received and used by your firm, and did not contain any assessment of known or reasonably foreseeable hazards of the ingredients. Additionally, the written hazard analysis identified as Section 8, Hazard Analysis Assessment, only listed the processing step "(b) (4) Metal Detection System (b) (4)", under a heading of "(b) (4)". No other processing steps were identified in this hazard analysis. Both hazard analyses did not identify the following known or reasonably foreseeable hazards: a) Nutrient toxicity or deficiency for pet food manufactured at your facility for cats and dogs. b) Mycotoxins were not assessed for ingredients susceptible to contamination. Your formulas include, in part, spelt, oats, and barley, intended for feeding to cats and dogs. Currently your firm conducts aflatoxin testing on grains received at your facility, but does not test for fumonisin or deoxynivalenol (DON) on any grain product or co-product.			
OBSERVATION 2 You did not identify and implement preventive controls to ensure that any hazards requiring a preventive control are significantly minimized or prevented. Specifically, your firm identified the preventive control of sanitation in your food safety plan under Section 11 - Sanitation Preventive Controls which lists the preventive control of Environmental Testing Control with swabbing			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Alec D Fabus, Investigator Alec D Fabus Investigator Signed By: 2002656008 Date Signed: 03-05-2026 12:42:56 X	
		DATE ISSUED 3/5/2026	

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and analysis for salmonella to be conducted (b) (4). At the time of the inspection, your environmental testing program had not yet been implemented as a verification activity for sanitation controls and environmental pathogen testing had not yet been performed. Additionally, your firm had identified the preventive control of metal detector under Section 10 - Process Preventive Control for the hazard of foreign material (metal). At the time of the inspection, the preventive control for metal detection was not fully implemented. Metal detectors were located at (b) (4) line, but no testing had been performed to verify the metal detectors were functional prior to 03/03/2026.			
OBSERVATION 3 You did not validate your identified process preventive control to adequately control the hazard as appropriate to the nature of the preventive control and its role in your food safety system. Specifically, your process control for pathogens at the (b) (4) step did not have a validation study available specific to your equipment being used that validates that the temperature of the (b) (4) and that the temperature of the product (b) (4) was adequate to control pathogens.			
OBSERVATION 4 Preventive control monitoring records are not complete. Specifically, your "Report - (b) (4) Parameters" logs prior to 03/03/2026 did not record any of the (b) (4) temperature values to be taken as your monitoring activity for the process control of pathogens at the (b) (4) step. Additionally, you were not able to locate the logs for the majority of February 2026.			
OBSERVATION 5 You did not establish appropriate written corrective action procedures for preventive controls. Specifically, your process control for pathogens at the (b) (4) step lists a critical limit of (b) (4) degrees celsius for the (b) (4) temperature of product (b) (4). Your "Report - (b) (4) Parameters" log recorded a			
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FOOD AND DRUG ADMINISTRATION

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(407) 475-4700 Fax: (407) 475-4768

DATE(S) OF INSPECTION

3/2/2026-3/5/2026

FEI NUMBER

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Carlo [nm] Ferrario, Plant Manager

FIRM NAME

Farmina Pet Food USA LLC

STREET ADDRESS

248 Sands Rd

CITY, STATE, ZIP CODE, COUNTRY

Reidsville, NC 27320-6522

TYPE ESTABLISHMENT INSPECTED

Pet Food Manufacturer

monitoring temperature of [REDACTED] degrees celsius on 3-3-2026, but no corrective action procedures were documented for the temperature deviation.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Alec D Fabus, Investigator

Alec D Fabus
Investigator
Signed By: 2002656008
Date Signed: 03-05-2026
12:42:56

X

DATE ISSUED

3/5/2026

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."