DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Atlanta District Office 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202 Industry Information: www.fda.gov/oc/industry	12/08/2025-12/12/2025
	FEI NUMBER 3004319366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Van H. Brown, CEO

FIRM NAME	STREET ADDRESS
Carolina Prime Pet, Inc	2040 Morganton Blvd SW
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lenoir, NC 28645	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) (WE) OBSERVED:

OBSERVATION 1

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 you food safety system.

Specifically,

Your food safety plan dated 01/27/2025 included a written hazard analysis (HA) for formed fillet products dated 11/21/2025, which covered Chicken Chips and Pork Chips. These products are (b) (4) pet treats that use ground raw proteins that are pressed into shapes. Your HA identified Salmonella spp. and Listeria monocytogenes as biological hazards requiring a preventive control. Your HA identified a process control named (b) (4))" as a process preventive control. Your HA identified the following (b) (4) temperatures and cooking times for "Meat Items" which covers chicken and pork chips: (b) (4) , then (b) (4) , (b) (4) (b) (4) , and a final step where the (b) (4) is set at (b) (4) . Between 12/08/2025 and 12/11/2025, we reviewed the production records for bulk chicken chips lot (b) (4) and pork chips lot (b) (4) . We confirmed the products were manufactured using procedures that matched those outlined in the hazard analysis. Firm management explained that they use general USDA guidance which indicates the cooking temperatures that are needed to control Salmonella spp. Further, you do not measure, monitor, or otherwise control the humidity of the (b) (4) during the cooking process. No validation documents were provided.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Digitally signed by Kyle D. Covill -S Date: 2025.12.16 07:16:21 -05'00'	Kyle D. Covill, Investigator Jessica E. Gore, NCDA Technical Trainer II John C. Francis, NCDA Feed Inspector	12/12/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Atlanta District Office 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202 Industry Information: www.fda.gov/oc/industry	12/08/2025-12/12/2025
	FEI NUMBER 3004319366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Van H. Brown, CEO

FIRM NAME	STREET ADDRESS
Carolina Prime Pet, Inc	2040 Morganton Blvd SW
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lenoir, NC 28645	Manufacturer

OBSERVATION 2
You did not take adequate precautions to prevent contamination of animal food.

This is a repeat observation from the previous inspection dated 11/04/2024-11/08/2024.

Specifically,
A. On 12/08/2025, on the (b) (4) production side, we observed Beef ST pet treat lot (b) (4) exiting the (b) (4) (b) (4) Former and being deposited in (b) (4) columns, (b) (4) stacked, onto (b) (4) racks that were lined with (b) (4) (b) (4) sheets. The (b) (4) sheets had (b) (4) debris that was covered with the newly formed product.

B. On 12/08/2025, we observed one (1) employee feeding (b) (4) racks with (b) (4) sheets through a (b) (4) washer that uses (b) (4) water applied at (b) (4) pounds per square inch of pressure to clean. Another employee received the (b) (4) as they exited the washer and placed them into the slots on an empty cart. We observed that the racks and the (b) (4) sheets still contained debris after passing through the (b) (4) washer and were being placed on the cart without removing the debris before the application of the sanitizer.

C. On 12/10/2025, we observed apparent rodent excreta (too many to count) in the raw ingredient cooler on the pallets and pallet rack brackets on the second tier of the shelving system. The pallets contained combo bins holding ingredients and products. The excreta appeared dry with a white film. Additionally, apparent rodent excreta were observed on the plastic covering each of two (2) combo bins containing chicken chips on the bottom row in the (b) (4) storage area located next to (b) (4) .

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Digitally signed by Kyle D. Covill -S Date: 2025.12.16 07:43:49 -05'00'	Kyle D. Covill, Investigator Jessica E. Gore, NCDA Technical Trainer II John C. Francis, NCDA Feed Inspector	12/12/2025

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 judgement, 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."