Table of Contents

SUMMARY

Inspection	
Operation ID and Name	284942: Nestle Purina Pet Care Co.

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

This directed, comprehensive Preventive Controls Surveillance Inspection of a pet food and treat manufacturer was conducted in accordance with, Compliance Program Guidance Manual 7371.000 Comprehensive Animal Food Inspection and accomplished as part of the Division of Human and Animal Food Operations West II fiscal year 2024 work plan per eNSpect Operation ID 284942.

Upon arrival to the firm, a Form FDA 482, Notice of Inspection was issued to Mr. Justin P. Wilkinson, Plant Manager, and most responsible person at the firm (**Attachment 2**).

The previous inspection was conducted by FDA on 01/30/2024. No Form FDA 483, Inspectional Observations was issued but one discussion item was presented to the firm management: 1) you did not determine and conduct appropriate supplier verification activities. The inspection was classified as No Action Indicated (NAI). The current inspection on 04/30-05/02/2024 covered the firm's food safety plan, hazard analysis, GMPs, employee training, complaints, pest control, management interviews, and associated records were reviewed. The firm has approximately (b)(4) employees and operates (b)(4), and office hours 8AM-4PM Monday through Friday. No refusals were encountered, no samples were collected, and no reconciliation exam was completed. The firm (b) (3) (A).

At the beginning of the inspection the FDA Firm Resources handout was given to firm management. Prior observations were reviewed with the firm and found to no longer be valid. All prior complaints were reviewed with the firm and closed out during the inspection.

At the conclusion of the inspection, a one item Form FDA 483, Inspectional Observations was issued to Mr. Justin P. Wilkinson, Plant Manager, citing the following:

- You did not conduct a reanalysis of your food safety plan as appropriate.

Management was reminded of the firm's responsibility to comply with the Food, Drug, and Cosmetic Act and failure to do so could result in action including Seizure, Injunction, and Civil or Criminal Penalties.

Program Assignment Codes Covered	
Program Assignment Code	**Program Assignment Title**
71015	PART 507 CGMP/PC INSPECTIONS
71R894	ANIMAL FOOD RISK DATA FORM

Summary of Objectionable Conditions on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
21 CFR 507.50	You did not conduct a reanalysis of your food safety plan as appropriate.	No Firm Response Submitted

Correction Statuses current at time report was signed.

Consumer Complaints Review

We followed up on previous complaints and there were no new complaints previously not known to FDA. The firm states that consumer complaints are handled at the corporate level within the Office of Consumer Affairs (OCA). (b)(4) (b)(4). OCA would then distribute the information to the proper manufacturing plant location.

Consumer Complaints	
Complaint ID	**Complaint Coverage**
156585	Not enough information in report to determine if this product is manufactured at this location.
160531	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
172673	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
177278	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
177495	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
179252	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was

Consumer Complaints	
Complaint ID	**Complaint Coverage**
	undetermined.
180845	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
185335	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
185468	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
185566	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
185881	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
185910	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
186236	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
186508	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
187117	The firm's complaint files were reviewed for the lot number provided. We were not able to determine a cause for the complaint. Either the firm did not have a similar complaint for the lot number or the investigation was undetermined.
44545	Complaint is from 2007, the firm does not have access to records that many years back.
46313	Complaint is from 2007, the firm does not have access to records that

Consumer Complaints	
Complaint ID	**Complaint Coverage**
	many years back.
47160	Complaint is from 2007, the firm does not have access to records that many years back.
48227	Complaint is from 2007, the firm does not have access to records that many years back.
48555	Complaint is from 2007, the firm does not have access to records that many years back.
48713	Complaint is from 2007, the firm does not have access to records that many years back.
48779	Complaint is from 2007, the firm does not have access to records that many years back.
50841	Complaint is from 2007, the firm does not have access to records that many years back.
52750	Complaint is from 2007, the firm does not have access to records that many years back.

ADMINISTRATIVE DATA

Administrative Data	
Firm	Nestle Purina Pet Care Co.
Physical Address	
Address Line 1	2200 Manufacturing Dr
City / State / ZIP	Clinton, IA 52732-6846
Phone	1-563-243-5510
Fax	1-563-243-0187
Mailing Address	
Address Line 1	2200 Manufacturing Dr
City / State / ZIP	Clinton, IA 52732-6846
Email Address	(b) (6)
Website	https://www.purina.com/
Inspection Date(s)	4/30/2024, 5/1/2024, 5/2/2024

FDA Inspection Participants
Participant Name and Title
Joseph Haynes, Investigator
Andrew Schaal, Investigator

FDA Team Members Not Present for the Whole Inspection
Lisa Kurt, Inspector for the Iowa Department of Agriculture was only present on 04/30/2024 and 05/01/2024.

Non-FDA Inspection Participants			
Participant	**Agency**	**Purpose for Being Present**	**Dates of Participation**
Lisa Kurt, Inspector	Iowa Department of Agriculture		5/1/2024; 4/30/2024

Issued 482 Forms	
On the date(s) below, credentials were presented and a "Form FDA 482, Notice of Inspection" (attached) was issued to the person listed.	
Date Issued	**Issued To**
4/30/2024	Justin P. Wilkinson, Plant Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Justin P. Wilkinson, Plant Manager
Person's Name and Title	Erika M. Jacobson, Quality Assurance Manager

FDA Form 483		
Description	**Date Issued**	**Issued To**
Original	May 02 2024 03:33PM	Justin P. Wilkinson, Plant Manager

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	Justin P. Wilkinson, Plant Manager	Industry Portal Representative
Email Address	(b) (6)	
Phone Number		
IPR/FMD Person		
Person's Name and Title	Erika M. Jacobson, Quality Assurance Manager	FMD-145 Recipient
Email Address	(b) (6)	
Phone Number		
*If a corporation		

Guidance Documents Given to the Firm
Firm management was provided the FDA Firm Resources handout.

HISTORY

(b) (3) (A)	

Hours of Operation	The firm operates (b)(4), and office hours 8AM-4PM Monday through Friday.
New or Current Firm Legal Name	Nestle Purina Pet Care Co.
Legal Status	Inc
State of Incorporation	MO
Year of Incorporation	1934
Additional Information	This report was written entirely by Andrew K. Schaal, Investigator. Any reference within the report to "we" or "us" refers to the inspection team members. NOTE: The Form FDA 482, Notice of Inspection and Form FDA 483, Inspectional Observations lists the legal name as Nestle Purina Pet Care Co., but the correct legal name is Nestle Purina Petcare Company and Mr. Justin P. Wilkinson's name should be spelled with an "I", not an "O" on the Form FDA 482. **The FMD-145 should be addressed to:** Erika M. Jacobson, Quality Assurance Manager 2200 Manufacturing Dr. Clinton, IA 52732 **All official correspondence should be addressed to:** Nina Leigh Krueger, CEO/President 801 Chouteau Ave. St. Louis, MO 63102 FOIA Notice: The firm believes that the exhibits collected during this inspection are proprietary/confidential information and were not provided with the intent for distribution to the public.

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	The firm is (b)(4)% wholesale. They receive approximately (b)(4)% of their ingredients from out of state and (b)(4)% of their finished product is shipped out of state to their other facilities and their top customer (b)(4).

Product Covered	Purina Pro Plan Sensitive Skin Shredded Salmon and Rice
Incoming	Yes
Received From	**Exhibit 3** shows rice is received from several suppliers. (b)(4) (b)(4) are located in (b)(4).

Outgoing	Yes
Sent To	Finished product is shipped to several of their sister plants located in Denver, CO, Davenport, IA, Atlanta, GA, Oklahoma City, OK, Dunkirk, NY, Flagstaff, AZ and Mechanicsburg, PA.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	Nestle Purina Petcare Company, Clinton, IA location is a pet food and pet treat manufacturer that manufactures dog/cat food and dog/cat treats. All products currently manufactured at this location are under the Purina label, except one brand of (b)(4) treats. They manufacture approximately (b)(4) products at this location.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Justin P. Wilkinson, Plant Manager
Roles and Authorities	Mr. Wilkinson has the authority at this location to prevent, detect, and correct violations. His responsibilities include but not limited to; overseeing all day-to-day operations, overall safety of operations, and personnel. Mr. Wilkinson was present at the beginning of the inspection for issuing the Form FDA 482, was present at the close-out meeting, and provided some information contained in this report.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Industry Portal Representative, Accompanied During the Inspection
Email Address	(b) (6)
Person #2	
Person's Name and Title	Erika M. Jacobson, Quality Assurance Manager
Roles and Authorities	Ms. Jacobson has the authority at this location to prevent, detect, and correct violations and stop inbound/outbound shipments. Her responsibilities include but not limited to; oversees the quality systems, audits, oversees the quality department and associates, and internal audits. Ms. Jacobson was present during the entire inspection, was present at the close-out meeting, and provided information contained in this report.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, FMD 145 Recipient, Accompanied During the Inspection
Email Address	(b) (6)
Person #3	
Person's Name and Title	(b) (6), (b) (7)(C), Systems Supervisor
Roles and Authorities	(b) (6), (b) (7)(C) provided information and documents pertaining to the food

	safety plan and hazard analysis. (b) (6), (b) (7)(C) was present during the entire inspection, was present at the close-out meeting, and provided information contained in this report.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #4	
Person's Name and Title	(b) (6), (b) (7)(C), Product Safety Team Leader
Roles and Authorities	(b) (6), (b) (7)(C) provided information and documents pertaining to the food safety plan, hazard analysis, and sanitation. (b) (6), (b) (7)(C) was present during the entire inspection, was present at the close-out meeting, and provided information contained in this report.
The following are applicable to this person	Interviewed, Accompanied During the Inspection
Person #5	
Person's Name and Title	(b) (6), (b) (7)(C), Microbiologist
Roles and Authorities	(b) (6), (b) (7)(C) oversees the Pathogen Monitoring Program (PMP). She explained and provided documents for their environmental monitoring program. (b) (6), (b) (7)(C) was present during part of the inspection and provided information contained in this report.
The following are applicable to this person	Interviewed

FIRM'S TRAINING PROGRAM

The firm maintains all training electronically in (b)(4). New hire training is provided on safety, food safety and hygiene, and on-the-job training. Job specific training and food safety is provided to employees and there are (b)(4) reviews and retraining. The firm has (b)(4) (b)(4) : Erika Jacobson, Quality Assurance Manager, (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) .

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage
The firm is a dog/cat food and dog/cat treat manufacturer that manufactures approximately (b)(4) products. In the first quarter of 2024 they manufactured approximately (b)(4) tons of dry kibble ((b)(4)/day) and (b)(4) tons of treats ((b)(4)/day). Raw ingredients are received via truck and rail (rice, tallow, corn gluten) and have (b)(4) . The facility has (b)(4) bulk storage bins for wheat, corn, rice (b)(4), barley, (b)(4) packing bins, frozen storage for raw meat ingredients, a warehousing area, and are currently (b)(4) . The firm operates the following equipment for their products:

Process Flow, Operations, and Product Coverage

- Dry Kibble (dog/cat)
  - (b)(4) mixer for batching, (b)(4) extruders with (b)(4) mixers, (b)(4) further processing lines (FP) for fat/(b)(4), and (b)(4) packaging lines.
- Treats (dog/cat)
  - (b)(4) extruders, (b)(4) coolers, (b)(4) dryers, and (b)(4) packaging lines.

Food Safety Plan (FSP)

The firm has a FSP for dry kibble and a FSP for treats and they are signed and dated. During this inspection we focused on the dry kibble FSP. The firm identified (b)(4) preventive controls (CCP) and (b)(4) operational prerequisite programs (OPRP) for the manufacturing of dry kibble. The numbers following the acronyms are not sequential but are legacy numbers.

(b)(4) – Raw Material Receiving – Grains
- Mycotoxins (Aflatoxin, Fumonisin, Vomitoxin)..
  - (b)(4) tested in QA Lab when received.
  - **Exhibit 5** shows testing results for rice.
- (b)(4) is tested randomly per their system.
- Recent testing results were reviewed, and no issues were found.

(b)(4) – Raw Material Receiving
- Industry History for Ingredients ((b)(4), vitamin D, acids, etc.).
- In-house Lab Testing.
- Recent testing results were reviewed, and no issues were found.

(b)(4) – (b)(4) Adds and (b)(4) Batching
- Critical Ingredients (vitamin D, thiamine, etc.).
- (b)(4).
- In-house Lab Testing.
- Recent testing results were reviewed, and no issues were found.

(b)(4) – Metal Detection
- (b)(4)
- Checked at (b)(4).
- Recent results were reviewed, and no issues were found.

(b)(4) – Salmonella/(b)(4)
- (b)(4) F at (b)(4)
- (b)(4) monitoring, samples collected.
- Recent results were reviewed, and no issues were found.

(b)(4) – Salmonella – (b)(4)
- Only on (b)(4).
- (b)(4) F at (b)(4).
- Cat food/treats and dental dog food.

Process Flow, Operations, and Product Coverage

Sanitation

We reviewed spreadsheets and documents for approximately six months and found no issues, QAL (b)(4) Sanitation Procedures, (b)(4) Master Sanitation Program, and QAL (b)(4) General House Keeping ((b)(4) cleaning). The firm uses (b)(4) for food contact surfaces, sanitation after (b)(4), flushing after (b)(4), and shut down cleaning approximately every (b)(4). Utensils are colors coded: White-finished product, Red-raw material, Yellow-floors/lower equipment/framework, and Orange-front of extruders/dryers.

Environmental Monitoring Program

We reviewed spreadsheets and documents for approximately six months and found no issues, St. (b)(4) Pathogen Monitoring in Dry Pet Food Factories and QAL (b)(4) for the specific Clinton, IA facility. The firm has a Pathogen Monitoring Program (PMP) that swabs approximately (b)(4) sites for *Salmonella spp.* and *Enterobacter* on a (b)(4) basis. No issues were found during the review of their PMP.

Finished Product Testing

The firm does finished-product testing for *Salmonella spp.* on (b)(4) prior to them being released for shipment. On the packaging lines, samples are collected every (b)(4), the samples are then (b)(4). The firm maintains a (b)(4) for product, (b)(4).

Animal Food by-product

The firm uses gray totes labeled as animal food waste and "Do Not Feed To Cattle or Other Ruminants". The firm ships these totes to (b)(4) for further processing and used for (b)(4).

MANUFACTURING CODES

All products produced use a best by date and manufacturing code. The manufacturing code consists of a 15-17 digit alpha-numeric code such as 415510821845L04-XX.

- (b)(4)
- 1082 = Clinton, IA plant code
- (b)(4)

RECALL PROCEDURES

The firm maintains a recall plan within their food safety plan. There have been no recalls unknown to FDA.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Inspection Observations	
Observation	**1**
Citation Text	You did not conduct a reanalysis of your food safety plan as appropriate.
Observation Details	Specifically, Nestle Purina Pet Care Co. was notified by a representative of the Food and Drug Administration regarding a new potential hazard in pet food manufactured at your facility. As of 04/30/2024, your local management team indicated that they were unaware of this new potential hazard and had not conducted a reanalysis of your food safety plan.
Citation Reference	21 CFR 507.50
Supporting Evidence and Relevance	In February 2024 you were notified by a representative of the FDA within the Center for Veterinary Medicine regarding complaints associated with a new potential hazard in pet food. Upon arrival to the facility on 04/30/2024, management was unaware of the complaints/new potential hazard in the pet food they were manufacturing. **Exhibit 1** shows that the last time the FSP was updated for reanalysis was on 10/16/2023 when it was signed by Mr. Justin Wilkinson.
Discussion With Management	On 04/30/2024, on-site management contacted Nestle Purina Petcare Company in St. Louis, MO. Mr. Justin Schmidt acknowledged talking to a CVM representative on February 6, 2024 regarding the complaints and potential new hazard. Mr. Schmidt stated that they had been working on the potential issue at the corporate level with their microbiologists and currently did not see it as a hazard. Mr. Schmidt stated that their product would not sustain pathogen growth due to the (b)(4) (b)(4). Mr. Schmidt also asked if we were aware that they had reached out to the FDA's Center for Veterinary Medicine (CVM) on January 19, 2024 regarding an increase in specific complaints and had a meeting with CVM. We told Mr. Schmidt that we were unaware of this meeting. Mr. Schmidt stated that they had addressed the observation, were continuing to work on the observation at the corporate level, but would formally respond with an email to FDA within 15 days.
Correction Status	No Firm Response Submitted

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

The close-out meeting was held on 05/02/2024 with the following individuals in attendance: Justin Wilkinson, Plant Manager, Erika Jacobson, Quality Assurance Manager, (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) on a phone call several Nestle Purina Petcare Company St. Louis, MO employees, including Justin Schmidt, Director of Quality Assurance, Joseph Haynes, FDA Investigator, and Andrew Schaal, FDA Investigator.

A Form FDA 483, Inspectional Observations (**Attachment 1**) was issued to Mr. Wilkinson. One observation was listed on the Form FDA 483 and was reviewed with Mr. Wilkinson, see Objectional Conditions and Management Response section for details.

We explained to Mr. Wilkinson that he has 15 days to provide a written response to the item listed on the Form FDA 483. I provided him with the memo for Electronic Submission of Correspondences and emailed the form to Erika Jacobson, which contains the email address ORAHAFWest2FirmResponses@fda.hhs.gov.

The firm was reminded of the firm's responsibility to comply with the Food, Drug, & Cosmetic Act and failure to do so could result in action including: Seizure, Injunction, and Civil or Criminal Penalties.

ADDITIONAL INFORMATION

Pest control is handled in house with (b)(4) monitoring of tin cats, sticky traps, (b)(4) , and outside bait stations.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Exhibit 1 - FSP Cover - Dry Kibble	1
1	Exhibit 5 - Rice Ingredient Test	1
2	Exhibit 2 - Hazard Analysis Dry Kibble	9
3	Exhibit 3 - Rice Supplier	1
4	Exhibit 4 - Common Ingredients	1

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	Issued 483	2
2	Form FDA 482 - Justin P Wilkinson - Nestle Purina	3

SIGNATURE

Andrew K Schaal
Investigator
Signed By: Andrew K. Schaal -S
Date Signed: 05-13-2024 07:33:17

Joseph R Haynes
Investigator
Signed By: Joseph R. Haynes -S
Date Signed: 05-13-2024 15:57:09