

Establishment Inspection Report

Nestle Purina Pet Care

Flagstaff, AZ 86004

FEI: 2018966

EI Start: 3/26/2013

EI End: 3/28/2013

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SUMMARY

A focused inspection/investigation of this pet food manufacturer (dry dog and cat food) was performed in response to a CORE directed assignment. The CORE incident investigation was conducted as a result in a spike in consumer complaints pertaining primarily to canine GI illnesses. The objective of the assignment was to provide samples and information concerning the following Purina Beneful products/implicated lot numbers: Playful Life/300810861500L10, Healthy Radiance/233510860449L10 and Original/302310862127L05. Additionally, an assessment was performed on the overall firm practices.

The previous inspection of this firm was conducted due to the following consumer complaints: 118497 and 118592. This inspection was performed on 1/12/11 and was classified as NAI. The FACTS assignment number for this current inspection is 1504446.

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Nestle Purina manufactures and distributes a total of 41 different dry dog and cat food products including Friskies and the Beneful product line.

At the conclusion of the inspection/investigation no FDA-483 was issued and no observations were found. The following samples were collected (more detailed found in the sample section of this report): 376187, 376188, 376189, 376190, 376191, and 376192.

ADMINISTRATIVE DATA

Inspected firm: Nestle Purina Pet Care
Location: 4700 E. Nestle Purina Avenue
Flagstaff, AZ 86004
Phone: 520-526-3645
FAX:
Mailing address: 4700 E. Nestle Purina Avenue
Flagstaff, AZ 86004

Dates of inspection: 3/26/2013, 3/27/2013, 3/28/2013
Days in the facility: 3
Participants: Timothy T. Kapsala, Investigator

The plant operates [REDACTED] (b) (4)

HISTORY

The company was incorporated in the state of Missouri in the year 2001.
This (b) (4) square foot facility has been at this location since June of 1975. This facility is (b) (4) located throughout the United States.

Corporate Headquarters for Nestle Purina Pet Care is located at the following address:

Nestle Purina Company
Checkerboard Square
St. Louis, MO 63164

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INTERSTATE COMMERCE

Nestle Purina's products are distributed (b) (4) wholesale under their own labels Alpo, Friskies, and Purina Products. (b) (4) percent of their finished product is distributed into interstate commerce. This facility distributes/ships to the following states/countries: (b) (4)

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Credentials were shown and notice of inspection was issued to (b) (6), Manager. Mr. (b) (6) stated that he was the most responsible person available during the initiation of the inspection. Amy Kerr, Plant Manager is the most responsible person at this facility. Ms. Kerr was available on the second day (3/27/13) of the inspection.

Key operating personnel and their functions/responsibilities are as follows:

Amy Kerr, Plant Manager

Ms. Kerr is the most responsible person at the firm. She oversees all the operations at the plant and is authorized to hire and fire management personnel.

Ms. Kerr reports to Mark Burns, Divisional Director of Production who is located at Corporate Headquarters. Mr. Burns was not available during the inspection.

(b) (6), Quality Assurance Manager

Responsibilities include overseeing the following: Quality control, ingredients, finished product, and sanitation.

Mr. (b) (6) reports to Amy Kerr, Plant Manager.

(b) (6), Assistant Quality Assurance Manager

Responsibilities include assisting in overseeing the following: Quality control, ingredients, finished product, and sanitation.

Ms. (b) (6) reports to (b) (6), Quality Assurance Manager

(b) (6), Production Manager

Responsibilities include the following: Oversees all of Production, hires, and fires production personnel.

Mr. (b) (6) reports to Amy Kerr, Plant Manager.

FMD-145: All correspondence pertaining to this inspection should be addressed to:

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Amy Kerr, Plant Manager
4700 E. Nestle Purina Ave.
Flagstaff, AZ 86004

FIRM'S TRAINING PROGRAM

Training consists of classroom, videos and on the job training with management and experienced personnel in their respective areas.

MANUFACTURING/DESIGN OPERATIONS

Production Assessment

- a. Production practices were observed and no observations were found.
- b. Mr. (b) (6) stated that there have been no equipment or process changes since September of 2012.
- c. Mr. (b) (6) stated that there are (b) (4) used in the formulation process.

At this location this company manufactures/processes 41 different dry dog and cat foods. The pet food is packaged in multi-layered paper bags ranging from 3 lbs. to 55 lbs. bags.

This (b) (4) square foot facility consists of a (b) (4) square foot manufacturing area and a (b) (4) square foot warehouse area.

Raw material ingredients are (b) (4)

In a separate operation (b) (4)

Mr. (b) (6) stated that the firm has Critical Control Points (CCPs) in place to ensure that the following parameters are met: (b) (4)

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[Redacted] (b) (4)

Filling

[Redacted] (b) (4)

PRODUCTION/DISTRIBUTION RECORDS

Finished Product Records

Finished product production records were reviewed for each of the implicated product/lots: Playful Life/300810861500L10, Healthy Radiance/233510860449L10 and Original/302310862127L05.

All the records were completed and no issues were found. The structure of the production record includes and comprises the following:

[Redacted] (b) (4)

Note: Mr. (b) (6) and Ms. (b) (6) stated that the computer system does not allow the product to be released if specifications are not met.

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Distribution of implicated lots

Refer to the tables below for the following distribution information: Product, lot number, fill line, customer, city and state.

Beneful Playful Life lot number 300810861500L10 (b) (4)		
Customer	City	State
(b) (4)	Sparks	NV
(b) (4)	Lathrop	CA
(b) (4)	Shafter	CA
(b) (4)	Porterville	CA
(b) (4)	Fontana	CA
(b) (4)	Paramount	CA
(b) (4)	Woodland	CA
(b) (4)	Rialto	CA
(b) (4)	Apple Valley	CA
(b) (4)	Phoenix	AZ
(b) (4)	Stockton	CA
(b) (4)	Ontario	CA
(b) (4)	Chandler	AZ
(b) (4)	Red Bluff	CA
(b) (4)	Tolleson	AZ
(b) (4)	Vacaville	CA
(b) (4)	Phoenix	AZ
(b) (4)	Buckeye	AZ
(b) (4)	Riverside	CA

Beneful Healthy Radiance lot number 233510860449L10 (b) (4)		
Customer	City	State
(b) (4)	Apple Valley	CA
(b) (4)	Buckeye	AZ
(b) (4)	Chandler	AZ
(b) (4)	El Monte	CA
(b) (4)	Fontana	CA
(b) (4)	Irvine	CA
(b) (4)	Kapolei	HI

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(b) (4)	Los Angeles	CA
	Mira Loma	CA
	Ontario	CA
	Paramount	CA
	Phoenix	AZ
	Phoenix	AZ
	Porterville	CA
	Red Bluff	CA
	Rialto	CA
	Riverside	CA
	Riverside	CA
	San Bernadino	CA
	Santa Fe Springs	CA
	Shafter	CA
	Sparks	NV
	Stockton	CA
	Tempe	AZ
	Tolleson	AZ
	Tolleson	AZ
	Vacaville	CA
West Sacramento	CA	
Woodland	CA	
Kapolei	HI	
Los Angeles	CA	

Beneful Original lot number 302310862127L05		(b) (4)
Customer	City	State
(b) (4)	Prescott Valley	AZ
	Tolleson	AZ
	Phoenix	AZ
	Kapolei	HI
	Stockton	CA
	Ontario	CA
	Stockton	CA
	Patterson	CA

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(b) (4)	Riverside	CA
	Tolleson	AZ
	Hilo	HI
	Mangere	AK
	Mira Loma	CA
	Stockton	CA
	Phoenix	AZ
	Sparks	NV
	Tolleson	AZ
	Riverside	CA
	Paramount	CA
	Long Beach	CA
	Tempe	AZ
	Vacaville	CA
	Commerce	CA
	San Bernardino	CA
	Irvine	CA
	Woodland	CA
	Shafter	CA
	Fontana	CA
	Phoenix	AZ
	Rialto	CA
	Los Angeles	CA
	Stockton	CA
Buckeye	AZ	
Red Bluff	CA	
Porterville	CA	
Apple Valley	CA	

Cleaning/line change-over

The firm performs a [redacted] (b) (4)

I reviewed the following "Clean-Up" records during the time-frame of each of the implicated lots and found no issues or problems:

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1. "[REDACTED] (b) (4)" which focuses on equipment, floors, and lines. The product contact equipment is checked and cleaned on a daily basis.
2. "[REDACTED] (b) (4)" which also covers equipment, floors and lines, but is more detailed.
3. "[REDACTED] (b) (4)" which specializes in detailed equipment cleaning.

I also reviewed the [REDACTED] (b) (4) which includes the following: air leaks, oil leaks, grease build-up, equipment failure, seals and proper storage of chemicals. No issues were found.

PRODUCT INGREDIENTS

Products/Implicated Lots

Product	Lot Number
Playful Life (B16)	300810861500L10
Healthy Radiance (B34)	233510860449L10
Original (237)	302310862127L05

a. All three products (B16, B34 and 237) listed above share the following ingredients:

1. Dog Vitamin [REDACTED] (b) (4).
2. Corn Yellow [REDACTED] (b) (4).
3. Amino Acid Lysine.
4. Potassium Chloride.
5. Gluten Corn Meal.
6. [REDACTED] (b) (4)
7. [REDACTED]
8. Vitamin E 50%.
9. Chicken By Product Meal.
10. Calcium Propionate.
11. Monocalcium Dicalcium
12. Calcium Phos Tribasic [REDACTED] (b) (4)
13. Acid Phospheric [REDACTED] (b) (4).
14. Choline Chloride.
15. Color Yellow #5.
16. Color Red #40.

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17. Acid Sorbic (b) (4)
18. (b) (4)
19. (b) (4) and Bone Meal.
20. Chicken Meal.
21. (b) (4).
22. Dicalcium Phosphate.
23. Wheat Whole.
24. Sugar White Granulated.
25. Salt.
26. (b) (4)
27. Propylene Glycol.

From the three products (B16, B34 and 237): The following ingredients were only found in B16:

1. Spinach Powder.
2. Oat Meal.
3. Egg (b) (4).
4. Tomato Powder (b) (4)

From the three products (B16, B34 and 237): The following ingredients were only found in B34:

1. (b) (4) Salmon (b) (4).

From the three products (B16, B34 and 237): The following ingredients were only found in B16 and 237:

1. (b) (4) Beef (b) (4)
2. Color Blue #2.

From the three products (B16, B34 and 237): The following ingredients were only found in B34 and 237:

1. Carrot (b) (4)
2. Color Yellow#6.

- b. Mr. (b) (6) stated that there have not been any new ingredients or changes in the formulation.

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- c. Mr. (b) (6) stated each individual ingredient for each product listed above is sourced from (b) (4).
- d. Mr. (b) (6) stated that there have not been any vendor changes (sources) since September of 2012.
- e. There are no (b) (4) from foreign sources; however the following ingredients originate from (b) (4) (b) (4), Choline Chloride (b) (4) Color Blue #2 FD&C, Color Yellow #5 FD&C, Color Red #40 and Color Yellow #6.
- f. Garlic oil is used in each of the three products and comprises less than (b) (4) of the total batch. (b) (4)

Below is the product/year that garlic oil first used as an ingredient

Original – 2001
Healthy Radiance - 2004
Playful Life – 2007

(b) (4)

(b) (4)

g. Corn Supplier's

The firm has the following corn supplier's/distributor's

(b) (4)

- h. Refer to the laboratory section of this report for corn (raw ingredient) mycotoxin results.

LABORATORY

The firm performs mycotoxin (aflatoxin and vomitoxin) analysis on every lot of corn that they receive. I reviewed all the test results (aflatoxin and vomitoxin) for all the lots (13 lots) of corn that were used in the manufacture of the following implicated products/lots: Playful Life/300810861500L10, Healthy Radiance/233510860449L10 and Original/302310862127L05. The firm had the following specifications; Aflatoxin limit: (b) (4); Vomitoxin limit: (b) (4). All

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of the lots were well within the specifications. Aflatoxin results ranged from (b) (4).
Vomitoxin results ranged from (b) (4)

The firm has written approved (b) (4) specs.
Example: (b) (4)

Minimum		Maximum	
Protein	(b) (4)	Protein	(b) (4)
(b) (4)			

The firm uses a LECO protein analyzer to assay for protein content. A small sample is collected and placed into the machine. The analyzer burns the sample to ash and measures nitrogen content, which is a measurement of protein content. (b) (4)

Mr. (b) (6) stated that the firm also performs routine contamination analysis on all lots of ingredients, but would not describe this analysis since the method is classified at the firm as proprietary information.

Finished product testing consists of the following test: Protein, fat, (b) (4). I reviewed the results for the implicated lots and everything was within specifications.

MANUFACTURING CODES

0345 1086 1216 L06 see below for break-down of code

(b) (4)

COMPLAINTS

(b) (6), Quality Assurance Manager stated that all complaints are handled through the corporate office in St. Louis, MO. Mr. (b) (6) stated that he was not aware any increase (spike) in consumer complaints. (See below for detailed complaint process).

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All complaints are handled at the corporate office in St Louis, MO. The complaints are handled in the following manner:

Consumer calls 1-800 #



RECALL PROCEDURES

Mr. (b) (6) stated that there have been no recalls in the last year. In the event of a recall, complete traceability is maintained from ingredients, ingredient suppliers, equipment used, finished product and customers.

REFUSALS

There were no refusals, however see the Additional Information section of this report.

ADDITIONAL INFORMATION

The firm allowed me to review records, but not obtain copies of records unless approved by the firm's legal counsel. Center personnel (CVM) informed me that this practice complies with the CFR's concerning pet food manufacturing.

SAMPLES COLLECTED

Note: There were no corn lots available that were used in the implicated lots or the lots collected.

The following samples were collected: 376187, 376188, 376189, 376190, 376191 and 376192.

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1. Two 15.5 lb bags of Purina Beneful Playful Life (dry dog food) lot 30081086 1615L10 were collected. **This is the same product and lot number of the implicated lot.**
 - A. Sample 376187 was collected for microbial analysis and sent to PRL-SW.
 - B. Sample 376188 was collected for mycotoxin and pesticide analysis and sent to KAN-DO Lab.

2. Two 15.5 lb bags of Purina Beneful Healthy Radiance (dry dog food) lot 302210860216L10 were collected. **The implicated lot (233510860449L10) was not available.** However the collected lot was the same product and filled on the same line (b)(4) as the implicated lot.
 - A. Sample 376189 was collected for microbial analysis and sent to PRL-SW.
 - B. Sample 376190 was collected for mycotoxin and pesticide analysis and sent to KAN-DO Lab.

3. Two 7 lb bags of Purina Beneful Original (dry dog food) lot 307210860934L05 were collected. **The implicated lot (302310862127L05) was not available.** However the collected lot was the same product and filled on the same line (b)(4) as the implicated lot.
 - C. Sample 376191 was collected for microbial analysis and sent to PRL-SW.
 - D. Sample 376192 was collected for mycotoxin and pesticide analysis and sent to KAN-DO Lab.

ATTACHMENTS

1. FDA-482 issued to (b)(6), Quality Assurance Manager.
2. CORE assignment (three pages).
3. CORE Incident Package (three pages).

(b)(6)

Timothy T. Kapsala, Investigator