

Establishment Inspection Report

Nestle Purina PetCare
Mechanicsburg, PA 17050-2817

FBI: 2527354
EI Start: 03/27/2013
EI End: 03/29/2013

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SUMMARY

This directed inspection of a pet food manufacturer was conducted under CP 7371.003, Feed Contaminants Program and CP 7371.009, BSE/Ruminant Feed Ban Inspections, as part of CORE FACTS ASID #1504446 OPID 6685356 due to an increased number of consumer complaints associated with Purina Beneful products during January and February 2013.

The previous inspection was conducted on 28 JUN 2011 by the Pennsylvania Department of Agriculture and was classified as NAI.

The current inspection revealed that the firm continues to operate as a dry pet food manufacturer. The firm does not manufacture ruminant feed. This inspection included a walkthrough, record review, document collection, and finished product sampling. All documentation that was collected at the request of CVM and CORE and was not used in this EIR will be captured in a memo, boxed up, and sent to Tami Cloyd, Veterinary Medical Officer, in College Park, MD.

A BSE inspection was also conducted during the inspection.

Samples 775888-775892 and 803349-803350 were collected during the inspection. An FDA-484, Receipt for Samples, was issued to Melvin V. Hennemann, Factory Manager, on 29 MAR 2013.

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Chrisopher Cowell, Head of Regulatory, located in the firm's corporate office in St. Louis, MO stated per the Food, Drug, and Cosmetic Act Section 414 (d)(4) with the definition of "recipe" (21 CFR 1.328) the firm is not able to provide the actual amounts or weights of individual ingredients that went into each batch of the implicated lots.

No FDA-483 was issued. No rodent, avian, or insect activity was observed.

ADMINISTRATIVE DATA

(This EIR was written by Brandi L. Garbutt, unless otherwise noted)

Inspected firm: Nestle Purina PetCare
Location: 6509 Brandy Ln
Mechanicsburg, PA 17050-2817
Phone: 717-697-0381
FAX:
Mailing address: 6509 Brandy Ln
Mechanicsburg, PA 17050-2817
Dates of inspection: 3/27/2013, 3/28/2013, 3/29/2013
Days in the facility: 3
Participants: Brandi L. Garbutt, Investigator
Brandon J. Brookens, Investigator

On 27 MAR 2013, an FDA-482, Notice of Inspection, was issued to Melvin V. Hennemann, Factory Manager. Also present during the Notice of Inspection was (b) (6), Quality Assurance Manager; (b) (6), Production Manager; and (b) (6), Assistant Quality Assurance Manager.

HISTORY

The firm's history has not changed since the last inspection on 23 OCT 2008. The firm continues to operate (b) (4). Gross annual sales could not be estimated. The firm's corporate office is located in St. Louis, MO.

Mr. Hennemann stated that he will be (b) (6) and (b) (4) will be (b) (4).

Mr. (b) (6) stated that the firm started testing for Salmonella during processing and in finished product samples in April 2012.

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Post-inspection correspondence should be addressed to:

Michael O'Brien, Factory Manager
Nestle Purina PetCare
6509 Brandy Lane
Mechanicsburg, PA 17050

INTERSTATE COMMERCE AND JURISDICTION

The firm continues to manufacture pet food for dogs and cats. Mr. (b) (6) stated that the firm produces approximately (b) (4) of pet food each year and of that amount, (b) (4) of product is the Beneful dog line alone. The firm operates (b) (4) of their products in interstate commerce via common carrier. Mr. Hennemann explained that the firm (b) (4)

. On 27 MAR 2013, I asked Mr. (b) (6) to provide me with the firm's distribution list for each of the implicated products. On 27 MAR 2013, Mr. Hennemann provided INV Brookens and I with product labeling and on 28 MAR 2013, Mr. (b) (4) provided us with an electronic copy of the distribution lists for:

- Healthy Radiance, 205510851121L02→Photographs of labeling are attached as **Exhibit 1**
- Beneful Original, 230810851735L06→Photographs of labeling are attached as **Exhibit 2**
- Healthy Fiesta, 224010850246L09→ Photographs of labeling are attached as **Exhibit 3**
- Playful Life, 232510850058L05→ Photographs of labeling are attached as **Exhibit 4**
- Healthy Weight, 227810850804L06→ Photographs of labeling are attached as **Exhibit 5**
- Healthy Weight, 229310852047L08
- Healthy Growth for Puppies, 235010851118L08→ Photographs of labeling are attached as **Exhibit 6**
- Healthy Radiance, 232210850830L05
- Healthy Radiance, 233810850152L07
- Playful Life, 228410852116L08

The electronic copies of the distribution lists are included on a CD labeled as **Exhibit 37** and can be found in the excel file titled "Distribution List Implicated Lots.xlsx".

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

(This section of the EIR was written by INV Brookens)

Mr. Melvin V. Hennemann, Factory Manager, oversees all employees, manufacturing and equipment operations, logistics, and shipping for the entire Mechanicsburg, PA facility. Mr. Hennemann stated that he is the most responsible person at the Mechanicsburg, PA plant and reports

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directly to Mr. John A. Baer, Vice President and Director of Manufacturing and Product Supply for the entire Nestle Purina Corporation. Mr. Hennemann also stated that he has hiring and firing capabilities. On 27 MAR 2013, INV Garbutt and I introduced ourselves and displayed credentials to Mr. Hennemann shortly after arriving at the firm. We also issued him the FDA-482, Notice of Inspection (NOI), because he stated that he is the most responsible. During the inspection, Mr. Hennemann provided us with mostly administrative information. He did not accompany us during sampling or observance of the production/packaging areas. Mr. Hennemann stated that he will be (b) (6) and that (b) (4). On 29 MAR 2013, INV Garbutt and I held a closeout meeting with management. During the meeting, INV Garbutt issued Mr. Hennemann an FDA-484, Receipt for Samples.

Mr. (b) (6) **Quality Assurance Manager**, oversees all product safety and quality programs for the Mechanicsburg, PA facility. Mr. (b) (6) reports directly to Melvin V. Hennemann, Factory Manager. Mr. (b) (6) stated that he recently joined the staff at the Mechanicsburg, PA facility, however, he explained that he was the QA Manager at other Nestle Purina facilities in previous years. On 27 MAR 2013, INV Garbutt and I introduced ourselves and displayed credentials to Mr. (b) (6) during the NOI issuance. Mr. (b) (6) accompanied us during the entire inspection. He accompanied us during sampling; as well as, the observance of the production and packaging areas. Mr. (b) (6) was our main contact during the inspection and provided us with most of the information and documentation that we requested. Mr. (b) (6) was also present during the closeout meeting on 29 MAR 2013.

(b) (6), **Materials Manager**, is responsible for the documentation and traceability of ingredients. Ms. (b) (6) reports to (b) (6), Controller. On 27 MAR 2013, INV Garbutt and I introduced ourselves and displayed credentials to Ms. (b) (6). She was present only during the NOI issuance and was not present during the closeout meeting on 29 MAR 2013. Ms. (b) (6) did not provide any documentation during the inspection.

(b) (6), **Production Manager**, supervises all employees in the production and packaging areas. Ms. (b) (6) reports directly to Melvin V. Hennemann, Factory Manager. On 27 MAR 2013, INV Garbutt and I introduced ourselves and displayed credentials to Ms. (b) (6). She was present during the NOI issuance. Ms. (b) (6) accompanied us during the entire inspection. She also accompanied us during sampling, as well as, the observance of the production and packaging areas. Ms. (b) (6) was not present during the closeout meeting on 29 MAR 2013.

(b) (6), **Assistant QA Manager**, oversees all quality personnel and assists with product safety and quality programs for the Mechanicsburg, PA facility. Mr. (b) (6) reports directly to (b) (6), Quality Assurance Manager. On 27 MAR 2013, INV Garbutt and I introduced ourselves and displayed credentials to Mr. (b) (6). Mr. (b) (6) was not present during the NOI issuance, but he arrived shortly after and accompanied us during the entire inspection. Mr. (b) (6) also accompanied us during sampling, as well as, the observance of the production and packaging areas. Mr. (b) (6) was present during the closeout meeting on 29 MAR 2013.

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(End INV Brookens)

MANUFACTURING/DESIGN OPERATIONS

This inspection focused on the manufacturing and production practices of the following implicated products:

<u>Manufacturing Code</u>	<u>Product</u>
205510851121L02	Healthy Radiance
230810851735L06	Beneful Original
224010850246L09	Healthy Fiesta
232510850058L05	Playful Life
227810850804L06	Healthy Weight
229310852047L08	Healthy Weight
235010851118L08	Healthy Growth for Puppies
232210850830L05	Healthy Radiance
233810850152L07	Healthy Radiance
228410852116L08	Playful Life

Mr. (b) (6) and Mr. Hennemann stated that the firm continues to have over (b) (6) different formulations of pet food. The firm continues to receive (b) (4). On 27 MAR 2013, Mr. (b) (6) and Ms. (b) (6) accompanied INV Brookens and I on a walkthrough of the firm. Mr. (b) (6) and Ms. (b) (6) explained the firm's manufacturing process.

Operational Flow Chart: (b) (4)

Ingredients such as grains, frozen meats, fats, oils, minerals, and vitamins are received by (b) (4)

(b) (4)

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(b) (4)

I asked Mr. (b) (6) if the firm calibrates these scales. Mr. (b) (4) stated that the scales are calibrated (b) (4) by an outside vendor and then (b) (4) the firm checks the accuracy using certified weights. I asked to review calibration records for the last four quarters. Mr. (b) (4) provided me with Certificate of Calibration #316430, dated 11/21/2011; Certificate of Calibration Record #327714, dated 3/2/2012; Certificate of Calibration Record #339436, dated 5/11/2012; and Certificate of Calibration Record #347735, dated 8/10/2013 from (b) (4) (b) (4) for Scale ID 5057. No deviations were noted.

(b) (4)

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(b) (4)

Mr. (b) (6) explained that in April 2012, the firm began testing (b) (4) product for Salmonella. Mr. (b) (6) stated that (b) (4), a sample is pulled (b) (4) and analyzed for Salmonella. The batch cannot be released until all (b) (4) samples come back negative. I asked Mr. (b) (6) if the firm utilizes a third party lab to complete the analysis. Mr. (b) (6) stated that all analyses are performed in-house on a VIDAS® system. The firm also analyzes finished product for protein and fat content, (b) (4).

I reviewed "Salmonella (SLM-II)" analyses for:

- Beneful Original: 04 NOV 2014, Lot Number: 130621-0 (Exhibit 9)
- Beneful Healthy Fiesta: 28 AUG 2012, Lot Number: 130411-0 (Exhibit 10)
- Beneful Playful Life: 21 NOV 2012, Lot Number: 130621-0 (Exhibit 11)
- Beneful Healthy Weight: 04 OCT 2012, Lot Number: 130425-0 (Exhibit 12)
- Beneful Healthy Weight: 20 OCT 2012, Lot Number: 130621-0 (Exhibit 13)
- Healthy Growth for Puppies: 16 DEC 2012, Lot Number: 130801-0 (Exhibit 14)
- Healthy Radiance: 18 NOV 2012, Lot Number: 130621-0 (Exhibit 15)
- Healthy Radiance: 03 DEC 2012, Lot Number: 130729-0 (Exhibit 16)
- Beneful Playful Life: 12 OCT 2012; Lot Number: 130525-1 (Exhibit 17)

No deviations were noted.

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The firm utilizes a color coded system for equipment and cleaning utensils; this is described as follows:

(b) (4)




On 28 MAR 2013, I asked Mr. (b) (6) if the facility has had any equipment changes since Sept 2012. (b) (6) Engineering provided Mr. (b) (6) with equipment upgrades to the facility since Sept 2012 as follows:

- (b) (4)
 -
 -
 -
 -
- 

I also asked Mr. (b) (6) if Purina has changed formulations for any of the above product lines. Mr. (b) (6) provided me with a list of formulation changes for the following products:

(b) (4)



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(b) (4)

I asked Mr. (b) (6) why choline chloride was added to the products. Mr. (b) (6) stated that choline chloride was required in order to meet the nutritional requirements sets forth by the Association of American Feed Control Officials (AAFCO). (b) (6) Buying, provided Mr. (b) (6) with the firm's suppliers of choline chloride and (b) (4). The firm received Choline Chloride (b) (4) on or around 10/15/12, 10/31/12, 11/15/12, 12/5/12, and 12/20/12 from (b) (4). The firm received (b) (4).

On 27 MAR 2013, I asked Mr. (b) (6) if there were any ingredients that were completely unique to a specific product or product line. Mr. (b) (6) stated that he would have to ask the formulation team that question. On 28 MAR 2013, Mr. (b) (6) stated that the formulation team located in (b) (4) told him that the only ingredient that is unique to a specific product is the avocados used in Purina Beneful Healthy Fiesta. All other ingredients are used in more than one product or extend into other product lines. INV Brookens asked Mr. (b) (6) how the firm receives the avocado and at what point in the manufacturing process is it added. Mr. (b) (6) stated that the firm receives (b) (4). I asked Mr. (b) (6) to provide me with the firm's avocado supplier. Mr. (b) (6) stated that the firm's avocado supplier is (b) (4).

On 27 MAR 2013, I asked Mr. (b) (6) to provide me with production records for each of the implicated products. Mr. (b) (6) stated that it would take a while to gather all of the documentation. On 28 MAR 2013, Mr. (b) (6) stated that he would be able to release which raw ingredients are used in each product, but he would not be able to release specific quantities of each ingredient per conversations with corporate; see *Refusals section of this EIR*. Mr. (b) (6) provided me with

- "Beneful Healthy Radiance Batch IDs - 205510851121L02" (Exhibit 26)
- "Beneful Fiesta Batch IDs - 224010850246L09" (Exhibit 27)
- "Beneful Batch IDs - 227810850804L06" (Exhibit 28)
- "Beneful Healthy Radiance Batch IDs - 228410852116L08" (Exhibit 29)

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- “Beneful Batch IDs - 229310852047L08” (Exhibit 30)
- “Beneful Batch IDs - 230810851735L06” (Exhibit 31)
- “Beneful Playful Life Batch IDs - 232510850058L05” (Exhibit 32)
- “Beneful Healthy Radiance Batch IDs - 233810850152L07” (Exhibit 33)
- “Beneful Health Growth For Puppies Batch IDs - 235010851118L08 & 235010851117L08” (Exhibit 34)

I also Mr. (b) (6) if he could provide me with the results of whatever tests the firm performed on each raw ingredient that went into the above mentioned batches. On 29 MAR 2013, Mr. (b) (6) provided me with an electronic copy of raw ingredient test results for each lot of product. These excel files can be found on the CD labeled as Exhibit 37.

I told Mr. (b) (6) that since garlic oil was a common ingredient in most of the Beneful products, I would need to collect the firm’s list of garlic oil suppliers. Mr. (b) (6) provided information and documentation related to the firm’s garlic oil suppliers. From 08 MAR 2012-12 FEB 2013, the firm received (b) (4) With the exception of one incident, in which the firm received (b) (4)

(b) (4) and the carrier is FedEx Freight.

On 29 MAR 2013, I asked Mr. (b) (6) if there was a record associated with production that would demonstrate that the product met the firm’s critical control point throughout the entire process. Mr. (b) (6) provided INV Brookens and I with “HACCP Reporting: Plant Summary Report” for each of the implicated products. Mr. (b) (6) explained that if a process deviation were to occur, an event would be created by the system. On 10/04/12, an event was created on (b) (4) for Beneful Healthy Weight, Lot 227810850804L06 (Exhibit 35). Exhibit 36 is an email documenting the root cause of the event and release of the product. No other deviations were noted.

MANUFACTURING CODES

The manufacturing code consists of a 12 digit number and Best By date. The product has a shelf of (b) (4) For example:

BEST BY: JAN 2014 301510852518L06

(b) (4)

COMPLAINTS

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Mr. Hennemann and Mr. (b) (6) explained that consumer complaints are handled by the Office of Consumer Affairs at the firm's corporate location in St. Louis, MO. Mr. Hennemann continues to receive notification of the complaints as a percentage. Mr. Hennemann stated that he reviews the complaints immediately with production and QA and also during monthly meeting. I requested a list of complaints for all Beneful products for 2012. Mr. (b) (6) stated that corporate wanted a copy of the complaints from our FACTS system. I explained that I could not give them a copy because they contained confidential consumer information. I did provide corporate with a list of manufacturing codes associated with each consumer complaint so they could cross reference and see if an FDA complaint was one that they received. Mr. (b) (6) provided me with an electronic copy of the firm's Beneful complaints. This file can be found on the CD labeled as **Exhibit 37** in an excel file titled "Consumer Complaint Verbatims.xlsx".

Complaint #105538, dated 11/27/2009: complainant alleged that her dog had symptoms after consuming "Purina Pro Plan Large Breed Real Chicken Formula, BEST BY: DEC 2010 917910850939L05". Complainant took her dog to the vet for treatment with IV fluids and blood work. Blood work results showed high calcium levels and dehydration. Pet is also given Purina Beggin Strips, Ol' Roy Sam Walton's Bird Dog Beef, Chicken, Vegetable, Peanut Butter, and Bacon flavor treats, and Milk Bone Natural Snacks. Complainant alleges the food has an "off" odor.

Firm Disposition: Complainant contacted manufacturer on 11/18/10. Purina received a sample of the dog food and said that the sample met all physical specifications, had no off odor, no infestation, and no mold

Complaint #73996, dated 01/28/2009: complainant alleged her dog experienced symptoms after consuming "Purina Healthy Morsels, BEST BY: DEC 2009 835510851535L04". The product was previously used with no reaction.

Firm Disposition: Complainant contacted manufacturer on 01/26/09. Verbatim case text was quoted as such "Consumer called about the dog urinating a lot after switching to the product. The dog ate the food for two days, drinking a lot of water. Took to the vet and nothing was found to be wrong with him. No gradual transition. No damage to the bag".

Complaint #84873, dated 04/30/2009: Complainant fed puppy "Purina Puppy Chow, BEST BY: MAR 2010, 908910852245L06". Approximately an hour after consumption, the puppy vomited, was lying still, and felt very cold. Complainant took the puppy to the emergency vet where she died after being there for about 2 hours.

Firm Disposition: Complainant contacted manufacturer on 4/26/06 and stated that he fed the puppy Pedigree Little Puppy Food before switching to the Purina product and did not transition the dog to the new food. Consumer alleged he was going to send the food to a private lab for testing. On 5/4/09, Purina received a sample of the food and concluded that the food met all physical specifications, had no off odor, no infestation, and no mold. On 5/5/09, Purina provided the results to the complainant and initiated a claim. On 7/16/09, Purina received return mail for the unclaimed letter and the phone number was "unavailable".

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Complaint #123999, dated 12/28/2011: See FACTS ASID #1370425 OPID #5905876 and Sample #732118 and 732119 for additional information about this complaint.

Firm Disposition: Complainant contacted manufacturer on multiple occasions. Complainant sent food, cat's blood, and water to be analyzed by a private lab. (b) (6) (b) (4), from the private lab contacted (b) (6) at Purina and stated, "Cesium was way to high- if it was a human, it would be enough to kill the human. That is why I thought I should call you. I feed Purina to my own and recommend it. Blood reflects what was found in the sample of food." The complainant (b) (6)

Complaint #120564, dated 05/06/2011: Complainant alleged that "Purina One Hairball Formula, 105510851613L02" changed their packaging, omitted ingredients, and changed the order of ingredients without specifying on the packaging that this was a new formulation. Complainant alleged that new formulation is making her cats sick.

Firm Disposition: Complainant contacted the manufacturer and wanted to know why they removed soy lecithin. Manufacturer never answered her question but sent transition bags and coupons.

Complaint #126113, dated 05/02/2012: Complainant's dog passed away suddenly and vet suspected that it may have been from "Beneful IncrediBites, BEST BY: SEPT 2012, 125110851812L05". Complainant alleged that the dog ate ¾ cup of dog food around 4PM, went for a ride with her in the truck, and vomited all of his food up and made strange breathing noises. Complainant took the dog to the hospital and vet said his temperature was unusually low. The dog began to have seizures and then vomited the dye from the dog food. Dog has always eaten this food and is not given any other treats. The dog died on (b) (6)

Firm Disposition: Complainant contacted the manufacturer on 5/2/12 and stated that she left the dog in the car while she picked her son up from school. When she came back, the dog vomited and was trying to breathe. She thought that the dog had gotten sick from being in the heat from the car ride. On 8/21/12, Purina received a sample of the food and stated that it met all physical specifications, had no off odor, no infestation, and no mold.

Complaint #130195, dated 01/16/2013: Complainant alleged that her dog vomited every day after consuming "Beneful Healthy Weight, BEST BY: OCT 2013, 229310852047L08". Complainant also feeds the dog rawhide beef chews and people food. On 01/16/13, (b) (6) of Quality Assurance for Nestle told complainant that the company has no other complaints for this product.

Firm Disposition: On 03/07/13, Purina contacted the complainant and left a message. Complainant has not returned the call.

Complaint #130389, dated 01/29/2013: Complainant alleged that her dog experienced symptoms after consuming "Beneful Healthy Radiance, BEST BY: JAN 2013, 232210850830L05". Complainant took the dog to the vet and blood work was performed. Results showed that the dog's liver enzymes were extremely elevated and the dog was slightly anemic. Complainant brought the dog home and treated it with Milk Thistle.

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Firm Disposition: On 01/29/13, Purina called the consumer and left a message. On 01/31/13, Purina sent a claims letter. On 02/28/13, Purina received a sample of the food and stated that it met all physical specifications, had no off odor, no infestation, and no mold.

Complaint #130416, dated 01/30/13: Complainant alleged that dog experienced symptoms after consuming "Beneful Playful Life, BEST BY: NOV 2013 232510850058L05". Complainant brought the dog to the vet and it was diagnosed with kidney failure. The dog was treated with antibiotics and switched to a Blue Buffalo product.

Firm Disposition: Complainant wanted compensation for vet bills. On 01/29/13, Purina sent complainant a claims letter.

The firm did not receive or have records of complaint 775882, 106916, 89932, 119840, 124655, 124167, 128823, 130236, 130237, 130715, 131263, and 131427. These complaints were related to GI upset, vomiting, and diarrhea. We did not observe any manufacturing conditions that would have contributed to these complaints.

RECALL PROCEDURES

The firm has not had a recall since the last inspection.

REFUSALS

Christopher Cowell, Head of Regulatory, located in the firm's corporate office in St. Louis, MO stated per the Food, Drug, and Cosmetic Act Section 414 (d)(4) with the definition of "recipe" (21 CFR 1.328) the firm is not able to provide the actual amounts or weights of individual ingredients that went into each batch of the implicated lots.

SAMPLES COLLECTED

Sample #775888, collected on 27 MAR 2013, consisted of 10/approximately 2 pound subs of ground yellow corn collected from bin #24.

The following samples were collected on 28 MAR 2013

Sample #775889 consisted of 20/Beneful Healthy Radiance, 3.5lb bags, BEST BY: FEB 2014 303910850429L01 in final package form.

Sample #775890 consisted of 20/Beneful Playful Life, 3.5lb bags, BEST BY: FEB 2014 304410851241L02 in final package form.

Sample #775891 consisted of 20/approximately 200 gram aseptically collected subs of Beneful Healthy Growth for Puppies, 31.1lb bags, BEST BY: DEC 2013 235010850819L07.

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Sample #775892 consisted of 20/ approximately 200 gram aseptically collected subs of Beneful Healthy Weight, 15.5lb bags, BEST BY: FEB 2014 305310851700L08.

Sample #803349 consisted of 20/ approximately 200 gram aseptically collected subs of Beneful Original, 15.5lb bags, BEST BY: JAN 2014 301510852518L06.

Sample #803350 consisted of 20/ approximately 200 gram aseptically collected subs of Beneful Healthy Fiesta, 7lb bags, BEST BY: FEB 2014 304010850517L09.

EXHIBITS COLLECTED

1. Photographs of Healthy Radiance Product Labeling, 4 pages
2. Photographs of Beneful Original Product Labeling, 4 pages
3. Photographs of Beneful Healthy Fiesta Product Labeling, 4 pages
4. Photographs of Beneful Playful Life Product Labeling, 4 pages
5. Photographs of Beneful Healthy Weight Product Labeling, 4 pages
6. Photographs of Beneful Healthy Growth for Puppies Product Labeling, 4 pages
7. Photograph of Vitamin E raw ingredient
8. Photograph of Tripotassium Citrate raw ingredient
9. Salmonella (SLM-I1) results for Beneful Original, dated 04 NOV 2012, 6 pages
10. Salmonella (SLM-I1) results for Beneful Healthy Fiesta, dated 28 AUG 2012, 2 pages
11. Salmonella (SLM-I1) results for Beneful Playful Life, dated 21 NOV 2012, 2 pages
12. Salmonella (SLM-I1) results for Beneful Healthy Weight, dated 04 OCT 2012, 5 pages
13. Salmonella (SLM-I1) results for Beneful Healthy Weight, dated 20 OCT 2012, 5 pages
14. Salmonella (SLM-I1) results for Beneful Healthy Growth for Puppies, dated 16 DEC 2012, 2 pages
15. Salmonella (SLM-I1) results for Beneful Healthy Radiance, dated 18 NOV 2012, 4 pages
16. Salmonella (SLM-I1) results for Beneful Healthy Radiance, dated 03 DEC 2012, 4 pages
17. Salmonella (SLM-I1) results for Beneful Playful Life, dated 12 OCT 2012, 4 pages
18. Beneful (b) (4) Formulation Change email dated 11/26/12
19. Beneful (b) (4) Formulation Change email dated 12/19/12
20. Beneful (b) (4) Formulation Change email dated 12/19/12
21. Beneful (b) (4) Formulation Change email dated 03/19/13
22. Beneful (b) (4) Formulation Change email dated 03/21/13
23. Beneful (b) (4) Formulation Change email dated 03/21/13
24. Beneful (b) (4) Formulation Change email dated 03/21/13
25. Beneful (b) (4) Formulation Changed email dated 03/22/13
26. Beneful Healthy Radiance Batch IDs - 205510851121L02, 2 pages
27. Beneful Fiesta Batch IDs - 224010850246L09, 2 pages

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Mechanicsburg, PA 17050-2817

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28. Beneful Batch IDs - 227810850804L06, 3 pages
29. Beneful Healthy Radiance Batch IDs - 228410852116L08, 2 pages
30. Beneful Batch IDs - 229310852047L08, 2 pages
31. Beneful Batch IDs - 230810851735L06, 2 pages
32. Beneful Playful Life Batch IDs - 232510850058L05, 2 pages
33. Beneful Healthy Radiance Batch IDs - 233810850152L07, 2 pages
34. Beneful Health Growth For Puppies Batch IDs - 235010851118L08 & 235010851117L08, 2 pages
35. HACCP Reporting: Plant Summary Report, generated 2013-03-29
36. Email entitled "Re: HACCP Event at MCB" dated October 04, 2012, 3 pages
37. CD of electronic records
38. Photo CD sealed with 415a

ATTACHMENTS

1. FDA-482, Notice of Inspection, issued to Melvin V. Hennemann, dated 03/27/13
2. FDA-484, Receipt for Samples, dated 03/29/13 (2 pages)
3. BSE Report

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Brandi L. Garbutt, Investigator



Brandon J. Brookens, Investigator