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SUMMARY

This directed inspection of a pet food manufacturer was initiated by FACTS Assignment 1504446, Operation ID 6670746, Canine Gastrointestinal Illnesses/Beneful Dry Dog Food), and was conducted under PAC 71C001 for CORE Animal Feeds Incidents. The firm is one of three Purina dry dog food facilities that were inspected simultaneously in response to a recent surge in consumer complaints about Beneful brand dry dog food. This inspection was also the initial GMP inspection of the firm by FDA, which was conducted per CPGM 7303.803 Domestic Food Safety, including investigation of Consumer Complaint 131052.

The firm manufactures Purina brands of dry pet food, such as Beneful, Purina Dog Chow, Puppy Chow, Alpo Prime Cuts, Cat Chow, Kitten Chow, and Friskies. The firm does not produce, store, or distribute feed for ruminants or other livestock.

The previous FDA inspection was conducted 2/2007, as a follow-up to Consumer Complaints 40310 and 40338 about Beneful dry dog food products, and covered manufacturing, storage of raw

materials, and product distribution. Samples were collected of other products that were produced during the same time as the two suspect lots (or within 48 hours of those lots), as well as a different lot of the Beneful Healthy Radiance, which included the same lot of Dried Green Beans. Each product contained the same ingredients from the same storage bins or lots except for the Dried Green Beans, which were only used in the Beneful Healthy Radiance and Beneful Healthy Weight. Documentary Samples were completed regarding the green beans used in the two lots listed in the complaints. No deviations were noted, and no FDA 483 was issued. Lab results were negative.

The firm was previously inspected 4/2010, by Oklahoma Department of Agriculture, Feed and Fertilizer Division as a State Contract inspection pursuant to FY10 Work Plans under CPGM 7371.009, 21 CFR 589.2000 BSE Rule. No deviations were noted, and no FDA 483 was issued.

The inspected facility has not been associated with any recalls since the previous inspection.

The current inspection covered the firm's receiving, storage, manufacturing, and distribution practices, as well as protocols for handling complaints, addressing an ingredient recall, and initiating a product recall. The firm was in direct and constant contact with the Purina corporate Regulatory Affairs office in St. Louis, MO during this inspection. Documentation was provided upon request after permission was obtained from the corporate office.

The firm refused photography, as a corporate policy. Information regarding the firm's corporate legal counsel was obtained. In addition, management was not allowed to read or sign an Affidavit that accompanied the sample collections. Management was allowed to sign only the FDA 484 Receipt for Samples.

No objectionable conditions were observed during this inspection, and no FDA 483 Inspectional Observations was issued at the conclusion of this inspection.

Samples of whole kernel corn, ground corn (both are ingredients in all products), and finished Beneful dog food products were collected during this inspection, as directed by the CORE assignment. Samples were also collected from the lot implicated in CC#131052. All samples were analyzed for *Salmonella*, *E.coli* O157:H7, and mycotoxins, per the CORE assignment.

The firm is registered under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The firm is also inspected by third-party auditors, as required by customers.

Documentation (regarding the firm's suppliers, ingredients used in Beneful products, and the firm's sanitation practices) was downloaded into the Food Shield system by DAL-DO ERC.

ADMINISTRATIVE DATA

Inspected firm:	Nestle Purina Pet Care
Location:	13900 N. Lincoln Blvd Edmond, OK 73013-3401

Phone:	405-748-8496
FAX:	405-748-8433
Mailing address:	13900 N. Lincoln Blvd Edmond, OK 73013-3401
Dates of inspection:	3/25/2013, 3/26/2013, 3/27/2013, 3/28/2013
Days in the facility:	4
Participants:	Jennifer Owens Dowdy, Investigator Adam C. Hipko, Investigator

On 3/25/2013, I, Jennifer Owens Dowdy, and Adam C. Hipko, Investigators, presented credentials to Mr. William J. Reiley, Plant Manager. Upon initiation of this inspection, we were joined by Ms. Wendy Meyer, Oklahoma State Department of Agriculture, Food and Forestry. Mr. Reiley stated that he is the most responsible person at the firm, and then he introduced Mr. (b) (6), Quality Assurance Manager, and Mr. (b) (6), Production Manager. Mr. (b) (6) accompanied us throughout this inspection, and he provided information and documentation for this report. The RFR brochure was given and explained to Mr. (b) (6) Mr. Reiley, Mr. (b) (6) and Mr. (b) (6) attended the close out meeting on 3/28/2013. Although Mr. Reiley signed the Receipts for Samples at the conclusion of this inspection, the corporate office refused permission for him to read and sign the FDA 463 Affidavit, in connection with the samples that were collected during this inspection.

On 3/25/2013, I provided Mr. William J. Reiley, Plant Manager, with a copy of the FDA document entitled "Information Sheet - Assessment of Re-inspection and Recall User Fees for FY 2012 by the FDA" which provides the statutory authority granted to FDA to collect user fees for re-inspections by FSMA, who will be assessed user fees, and the rates. I also presented a copy of an information sheet regarding the bi-annual registration update requirement under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Ms. Meyer was present as an observer throughout this inspection and assisted with the sample collections on the second day of this inspection. She was also present during the close out meeting with management on 3/28/2013.

For this report, the term "we" refers to the Investigators (Jennifer Owens Dowdy and Adam Hipko, FDA and Wendy Meyer, OK State Department of Agriculture), collectively.

The term "NPPC" denotes the Nestle Purina Pet Care (parent company) corporate headquarters in St. Louis, MO, and "NPPC-OKC" denotes the inspected facility.

Except where noted, this report was written by Jennifer Owens Dowdy, Investigator.

HISTORY

The inspected firm is among Nestle Purina's largest pet food manufacturing facilities in the US. Nestle, SA (a publicly-traded, international corporation) acquired this Purina facility in 2001, and it is operated as a wholly owned subsidiary of Nestle Purina Pet Care, Checkerboard Square, St. Louis, MO 63164. The firm's website is *www.purina.com* and the CEO of Nestle Purina Pet Care is W. Patrick McGinnis. Other similar facilities are located in Flagstaff, AZ and Mechanicsburg, PA. Inspections of these facilities were initiated concurrently with this inspection by FDA, in response to a surge in consumer complaints regarding gastrointestinal illness in dogs after feeding Beneful dog food products. These three facilities were identified more often than others, as the sources of the products reported in the consumer complaints (received from January 2013 through February 2013).

The inspected facility has operated from this location for approximately 42 years. All products manufactured here are Nestle Purina brand names; the firm does not manufacture pet foods for third parties. Currently, production covers more than 35 different Nestle Purina brands of packaged dry pet foods for canine and feline pets). The firm produces more than (b) (4) of product annually, which is approximately (b) (4) per month. The firm stocks approximately (b) (4) different ingredients from (b) (4) vendors. The firm ships between (b) (4) unit loads per month, and the distribution area covers (b) (4). Management estimated that the Beneful dog food products account for (b) (4) of the firm's business.

Although some Purina brands of pet foods were affected by the 2007 recall due to wheat gluten tainted with melamine, this facility did not receive any of the affected ingredients, and did manufacture any of those products. The inspected facility has not been associated with any product recalls since the previous FDA inspection in February 2007, which was to follow-up on two consumer complaints about GI illness after feeding Beneful dog food. That inspection revealed no objectionable conditions, and product and ingredients (green beans) sample analyses were negative and/or in compliance.

The firm has (b) (4) .

All post-inspectional correspondence should be addressed to:
Mr. William Reiley, Plant Manager
Nestle Purina Pet Care
13900 N. Lincoln Blvd.
Edmond, OK 73013-3401

The firm is registered under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The firm is also inspected by third-party auditors, as required by customers.

INTERSTATE COMMERCE

The firm receives raw materials in bulk via (b) (4), as well as in (b) (4) (on pallets). Commodities such as whole kernel corn (b) (4). Some ingredients are received in (b) (4). Management estimated that (b) (4) of raw materials and packaging originate outside of Oklahoma.

Examples of vendors supplying ingredients used in the Beneful dog food products include:

(b) (4)

All products are distributed in packaged form. Management stated that the firm distributes packaged pet food products to retailers' distribution centers in (b) (4). Major customers include (b) (4). Management estimated that (b) (4) of products are bound for destinations outside of Oklahoma.

JURISDICTION

The firm manufactures, packages, and distributes Purina brands of dry pet food, such as Beneful, Purina Dog Chow, Puppy Chow, Alpo Prime Cuts, Cat Chow, Kitten Chow, and Friskies. The firm does not produce, store, or distribute feed for ruminants or other livestock. See **Exhibit 1:** List of products manufactured since August 2012.

Products are packaged for retail sale in bags ranging from 3.5 lbs to 55 lbs. Management estimated that the Beneful dog food products constitute approximately (b) (4) of the firm's production.

The firm is 100% wholesale. All products are transported by commercial carriers (contracted by NPPC or by the customer) to retailers' distribution centers in (b) (4). Major customers include (b) (4). Management estimated that (b) (4) of products are bound for destinations outside of Oklahoma.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. William J. Reiley, Plant Manager, identified himself as the most responsible individual at the firm. Mr. Reiley has been with the firm for over 14 years. He is responsible for the overall performance of the firm, including fiscal, production, and distribution. With few exceptions (as described below), all personnel at this location report to him. Mr. Reiley reports to Mike Burns, Vice President of Manufacturing, Nestle Purina Pet Care, St. Louis, MO. Mr. Reiley was present at the firm during this inspection, received the FDA 482 Notice of Inspection, and attended the daily update meetings. He also attended the close out meeting on 3/28/2013, and he signed the Receipts for Samples at the conclusion of this inspection; however, the corporate office refused permission for

him to read and sign the FDA 463 Affidavit, in connection with the samples that were collected during this inspection.

Mr. (b) (6), Quality Assurance Manager, has worked at the firm for approximately two years. He is responsible for the Quality and Product Safety programs for the firm. Mr. (b) (6) manages the on-site QA laboratory, including a team of (b) technicians. He is also responsible for investigating and documenting issues related to product complaints. Mr. (b) (6) duties encompass managing all product quality testing (including environmental tests, in-bound ingredients testing, etc.), assuring product evaluation (such as protein content, product standards, etc.), and maintaining documentation. Mr. (b) (6) also conducts recall exercises (trace-back of ingredients and/or finished products) on a regular basis. Mr. (b) (6) reports to Mr. Chris Cowell, Regulatory Affairs, St. Louis, MO. Mr. (b) (6) accompanied us throughout this inspection, and he provided information and documentation for this report. Mr. (b) (6) conferred frequently with the corporate office in St. Louis, MO, and provided explanation regarding the firm's refusal of photography, the accessibility of documentation, and refusal to permit Mr. Reiley, Plant Manager, to read and sign FDA Form 463, Affidavit regarding the samples that were collected during this inspection. Mr. (b) (6) compiled extensive documentation regarding the trace-back of ingredients, product distribution records, and quality and sanitation records, in connection with the implicated product lots. Mr. (b) (6) coordinated the daily up-date meetings attended by management. Mr. (b) (6) also coordinated the availability of products, ingredients, and records for the sample collections. He attended the close out meeting on 3/28/2013.

Mr. (b) (6), Production Manager, has been at this facility for approximately two years. He was previously the Production Manager at the Flagstaff, AZ, plant. Mr. (b) (6) is responsible for personnel on (b) (4), and manages (b) employees at this facility. His duties encompass scheduling the production based on direction from the corporate Operations Planning Department, St. Louis, MO. Mr. (b) (6) manages the plant's (b) production employees and the (b) (4) sanitation team, and he reports to the Plant Manager, William Reiley. Mr. (b) (6) accompanied us during portions of this inspection; he provided explanation about production, and described sanitation practices at the plant. Mr. (b) (6) attended the close out meeting on 3/28/2013.

(b) (6), Materials Manager, has worked at the inspected facility for more than 22 years. He is responsible for receiving , storage, and records of raw materials, including bulk delivery and storage of commodities such as whole kernel corn, soybean hulls, soybean oil, and rice. (b) (4) employees report to Mr. (b) (6) and he reports to Mr. (b) (6), NPPC Logistics Manager. Mr. (b) (6) accompanied us during the walk-through of the receiving /raw materials storage, and assisted Investigator Hipko as the corn and ground corn samples were collected; Mr. (b) (6) also provided copies of the receiving documentation, upon request.

(b) (6), Transportation Manager, has been with the firm for approximately 17 years. Previously, she worked in the QA Department. (b) (4) employees report to her, and Ms. (b) (6) reports to Mr. (b) (6), NPPC Logistics Manager. Ms. (b) (6) oversees the distribution processes, including picking, loading, and evaluating the condition of the trailers before product is loaded. Ms. (b) (6) provided information about the distribution of Beneful products.

This section addresses each point of the directives of the CORE assignment.

COORDINATED OUTBREAK RESPONSE & EVALUATION FINDINGS

*This paragraph **** REDACTION NEEDED *****

A recent surge in consumer complaints related to Beneful dog food prompted FDA to initiate this investigation by the Coordinated Outbreak Response and Evaluation Network. This investigation simultaneously covered Nestle Purina Pet Care manufacturing plants located in OK, AZ, and PA. Complaints reported mostly dog GI illness; some neuro; no human illnesses. Of 133 consumer complaints received since March 2011, approximately 92 were received during the period beginning January 2013 (through February 2013). Product collected by FDA related to five consumer complaints was negative for *Salmonella* and *E. coli* O157:H7, negative for *Staphylococcus* and *Bacillus* toxins, and in compliance for mycotoxins. Among the consumer complaints where product information was provided, the facilities in PA, AZ, and OK were identified as the source of the reported products more often than other US Nestle Purina plants. For these reasons, CORE directed GMP inspections of the facilities, as well as product sampling and record collection of the implicated lots.

For the NPPC-OKC facility, CORE provided the following complaint/product information, which was shared with the firm during this investigation:

Complaint	Lot Code	Product
111824	2 222 1087 1346 L12	Healthy Radiance
114477	3 024 1087 0029 L12	Healthy Weight
113504	2 345 1087 2310 L07	Healthy Radiance
115487	2 357 1087 1314 L07	Original

During this inspection, one full pallet of Beneful Original (42-lb bags) Lot #2 357 1087 1314 L07 (manufacturing date 12/22/2012) was still on hand in the warehouse at the firm. Samples and manufacturing records were collected on 3/26/2013. None of the other three implicated lots (Radiance, manufactured on 8/9 and 12/10/2012; and Healthy Weight, manufactured on 1/24/2013) were remaining at the facility.

Product Ingredients/Ingredients Focus

Mr. (b) (6) stated that all formulations are proprietary information. Lists of ingredients for the Beneful products were obtained and compared to labeling; no deviations were noted. Mr. (b) (6) stated that all formulations are issued by the NPPC nutritionists; no formulation deviations are authorized or made at the plant level.

The firm provided a list of products manufactured since August 2012 (the earliest date of manufacturing of the implicated lots was 8/9/2012). See **Exhibit 1:** List of products manufactured since August 2012. Mr. (b) (6) stated that no new ingredients had been used, and no formulation alterations had been made for "quite some time" and that all formulation changes occur at NPPC. Mr. (b) (6) stated that suppliers have remained constant during that period of time, as well. He

further explained that the source of some commodities (such as corn and soybean hulls) may vary due to pricing; however, those decisions are made by NPPC.

With the exceptions of the additional ingredients used in the Healthy Weight and Radiance varieties, all Beneful dog foods produced by the inspected plant contain the same ingredients as Beneful Original, and all ingredients are generally from common suppliers. Mr. (b) (6) stated that suppliers have remained constant, since September 2012.

With regard to (b) (4), Mr. Reiley verified that although ingredients are generally supplied by US vendors, the NPPC office informed him that some of the (b) (4) components of the (b) (4) may be imported.

The firm uses the following oils in Beneful products:

(b) (4)

See **Exhibit 2:** List of Sources of Oils used in Beneful products

Review of formulations was limited by NPPC (as proprietary information); however, when asked whether the Beneful formulations contained any ingredients or sources of ingredients that are not used in other Purina products manufactured at this facility, Mr. (b) (6) and Mr. (b) (6) responded that Beneful products do not contain any ingredient that is exclusively in the Beneful products.

Corn is a component of the products manufactured at this facility, and corn is an ingredient in the Beneful products. Records were obtained to identify the source of corn used in the implicated lots of Beneful Original, as well as the lots of Healthy Weight and Radiance that were sampled. All in-bound corn is tested for aflatoxin before it is allowed to be unloaded; loads are rejected if results exceed (b) (4). Records of these tests were obtained. See **Exhibit 3:** Ingredients tests (76 pages).

Finished Product Records

Due to the volume of products made at this plant ((b) (4) per month and (b) (4)), production records are voluminous. Mr. (b) (6) explained that formulations are proprietary information but he agreed to provide production records pertaining to the implicated lots of Beneful Original (manufactured during December 2012), as well as for the recently-produced lots of Beneful Healthy Weight and Beneful Radiance (manufactured March 23, 2013). The Beneful products are run on (b) (4) Finished product testing records for the implicated products were collected. See **Exhibit 4:** Finished Product Testing by QA (8 pages)

Sampling – Finished Products and Ingredients

Mr. (b) (6) stated that finished products in the warehouse generally turn over (b) (4). During this inspection one full pallet of Beneful Original (42-lb bags) Lot #2 357 1087 1314 L07

was still on hand in the warehouse at the firm. Samples and manufacturing records were collected on 3/26/2013. None of the other three lots (Healthy Weight and Radiance) were remaining at the facility; we collected samples of these varieties from the recent run on 3/22 & 25/2013. In addition, samples of whole kernel corn and ground corn were collected. See **SAMPLES COLLECTED** section.

Production Assessment

Production was observed during the inspection: Friskies Seafood Sensations, Lot # 3 054 1087 1711 L06, was running early on 3/25/2013 and Beneful Healthy Weight, Lot #3 086 1087 1507 L01, was running on 3/27/2013. No GMP deviations were noted. See **MANUFACTURING OPERATIONS** section. Mr. (b) (6) stated that production is organized to meet orders efficiently, and that no manufacturing changes have occurred in the time period from September 2012 to date. He explained that during the week of 9/3/2012, the plant floor converted to (b) (4); however, this change would not have had any effect on production. He said the change occurred at start up, converting the inventory records. Mr. (b) (6) later stated that the firm had implemented a new (b) (4) (which affects only brands that take dye) on 3/18/2013. No (b) (4) were observed being used in production; Mr. (b) (6) verified that no (b) (4) are used during manufacturing of products.

Consumer Complaints

The firm does not have a written protocol for handling complaints. Mr. (b) (6) explained that all consumer complaints are received by the Office of Consumer Affairs at NPPC; no one at the plant level has direct contact with consumers. Reports of complaints are not received or investigated based on the individual complaint that was received at NPPC. When asked whether or not complaints had been received regarding the Beneful dog food products, Mr. (b) (6) stated that he receives a monthly report that has been compiled by NPPC, which categorizes the complaints as to issue, i.e., taste, texture, odor, etc., rather than by product name. He did not know whether or not an increase in complaints regarding the Beneful products had occurred. See **COMPLAINTS** section.

FIRM'S TRAINING PROGRAM

The firm provides orientation (food safety and OSHA safety) to all employees. Safety training is conducted by the Safety Manager; QA Manager or Team Leaders conduct food safety trainings. Mr. (b) (6) and Mr. (b) (6) are HACCP-trained. By corporate direction, GMP trainings must cover (b) (4) topics annually, so Team Meetings are conducted on a (b) (4), led by either the Team Leader or the QA Team. These meetings are generally "stand and discuss" types of meetings, held for each shift. Personnel records reflect attendance because employs must go online and "sign-off" to records their attendance. (b) (4) training on general compliance and security are also required.

MANUFACTURING OPERATIONS

The inspected facility was constructed by Ralston Purina in 1971. The plant, storage, and parking cover approximately (b) (4). The property is chain-link-fenced, and access is through a guarded

entry. The property is situated with (b) (4). The firm is supplied (b) (4). The plant was improved and expanded prior to Nestle's acquisition of the firm in 2001; further upgrades to equipment were made during the past 10 years. I observed that all food contact surfaces are (b) (4). Mr. (b) (6) stated that most equipment has been modernized or replaced; however, the (b) (4) are part of the original equipment. The plant operates on (b) (4).

Bulk storage includes a grain elevator (b) (4) The firm has a (b) (4) (b) (4) which holds meat products. The (b) (4) includes (b) (4) with elevated docks. (b) (4) doors are dedicated to trash collection.

RECEIVING AND STORAGE

(b) (4)

During this inspection, bottom door seals were observed intact and floors swept. Mr. (b) (6) told me that spills are swept as they occur, and that all employees are responsible for such maintenance.

PRODUCTION

(b) (4)

(b) (4)

[redacted]

During the current inspection, the firm was making Friskies Seafood Sensations, 16-lb bags, Lot #3 054 1087 1711 L06. We observed the production process, as follows:

(b) (4)

[redacted]

(b) (4)

Exhibit 5: Examples of product labeling (2 pages)

SANITATION

Sanitation at the firm is addressed by production employees, plus an (b) (4)-person sanitation team. The sanitation schedule covers (b) (4) routines. Mr. (b) (6) stated that the firm performs approximately (b) (4) per month. See **Exhibit 6:** Review Worksheet for Production Lines – All Sanitation and (b) (4) Tasks (4 pages).

(b) (4)

Approximately (b) (4) of equipment is CIP, and the firm uses (b) (4) Each production and packaging station uses a check-list for cleaning and sanitizing, which lists all equipment in the station, and requires pre-production review by a team leader. See **Exhibit 7:** Sanitation for Lines 2, 7, and 12 (19 pages).

Pest control is handled internally by a (b) (4)-man team, as part of the Product Safety Department. These employees are licensed pest-chemical applicators, and they interface with Mr. (b) (6) He explained that the pest control is "routine" and is based on the lifecycle of the insects. He stated that rodent activity was minimal. I reviewed the pest control log from 4/27/2012 though current; no deviations were noted. During this inspection, no pests and no evidence of pests were observed.

Upon arriving at the firm, we observed bird activity at the southwest side of the building, where the waste trailers were parked. Mr. (b) (6) explained that these trailers contained waste and by-products, and that the firm had made multiple unsuccessful attempts to stop the scavenger birds. No other birds were observed elsewhere on the property or inside the facility.

The firm is serviced by (b) (4), which picks up the open waste trailers and replaces them with empty trailers on a daily basis. Mr. (b) (6) said there are always five or six waste trailers on the property.

Mr. (b) (6) stated that the firm seldom (b) (4), as required by the firm.

QUALITY & FOOD SAFETY

Upon arrival, all corn deliveries are tested for aflatoxin using a (b) (4) system: (b) (4) are tested and must be within limits (combined); (b) (4) are sampled with a pneumatic probe. Threshold is (b) (4); if negative then the load is tested for vomitoxin (limit (b) (4)). The firm receives loads of corn (b) (4) Records were reviewed for 3/1-3/24/2013; two ((b) (4) loads were rejected during the past 25 days.

The firm has magnets strategically placed throughout the production cycle. These magnets are challenged randomly during each shift. A pull test is conducted for every magnet (b) (4). Magnet performance is rated "Good-Fair-Bad-Very Bad; magnets are replaced at Bad or Very Bad ratings. Records of the pull tests conducted on 12/8/2012 and 12/10 2012 were reviewed; no deviations were noted.

Scales at the add-in stations and on the packaging lines were noted to have been calibrated by (b) (4), on 11/14/2012. Mr. (b) (6) said scales are calibrated (b) (4)

Protein content is measured on every bank during every production run on every shift. Variations are corrected by (b) (4)

Members of the firm's Food Safety Team (Mr. (b) (6) QA Team Leaders, Mr. (b) (6) and Production Team Leaders, and Mr. (b) (6) are also on the HACCP team. The firm's written HACCP plan denotes one critical control point: the (b) (4)

The on-site lab is staffed with (b) technicians each shift. Routine tests performed include in-line protein contents, NIR, proteins in finished product, color analysis, and (b) (4) mite testing.

The firm has a Pathogen Monitoring Program. Environmental swabs test for *Salmonella* weekly, on pre-determined locations, close to product areas. Maximum limit is (b) (4). If an issue arises in the Zone 1, then production is stopped and cleaning ensues; then the area is re-tested and four or five swabs in the expanded area are taken. If a high count is noted, then the product is tested. In that instance, Mr. (b) (6) would notify NCCP, and NCCP would have to release the product for distribution. Mr. (b) (6) cannot release product in this instance; he must send an email showing negative results from the subsequent swabs. I reviewed records of the environmental tests for the week of 3/18/2013; no deviations were noted. We obtained the records of environmental testing for the dates the implicated products were manufactured. See **Exhibit 8:** Environmental Testing Results (10 pages).

The firm tests samples of finished products from the beginning of each run (each day code). Tests are for protein content, and sensory (texture, odor, size, etc.) specifications. Samples are obtained and tested at the QA station in the packaging area. See **Exhibit 4:** Finished Product Testing (8 pages).

Water supply used at the plant is municipal, from Oklahoma City. Micro testing is conducted by the plant (b) (4), and chlorine tests are conducted (b) (4) water is tested for metal (b) (4)

SHIPPING AND DISTRIBUTION
Mr. (b) (6) stated that the contents of the warehouse generally turns over (b) (4). Finished products on wrapped pallets rare marked with an adhesive label with bar code and manufacturing codes upon entry to the warehouse. During this inspection, I observed that like products are grouped together, more by manufacturing date rather than variety. Any product that is placed on "hold" is marked with yellow hazard tape until it is taken off hold by QA.

Mr. (b) (6) stated that both NCCP and the firm's traffic office contract for commercial carriers to transport finished products; some customers may also use their own fleet. Ms. (b) (6) Transportation Manager, stated that trailers are visually inspected prior to loading. Trailers deemed to be in unsatisfactory condition are rejected and the carrier is notified. An inspection and load verification check-box is stamped on the pick sheet for each trailer, and must be initialed by the loader before the driver receives the seal. Seal numbers are noted on the dispatch/delivery record, and seals are applied by the drivers. The seal is verified by the security guard as the truck departs.

The distribution records pertaining to the implicated lots of Beneful dog food products manufactured at NPPC-OKC were collected. See **Exhibit 9:** Distribution Records (white binder).

MANUFACTURING CODES
The firm's manufacturing code is stamped as the product is bagged. The code does not indicate the product. The manufacturing code follows this pattern:

(b) (4)

For example: **2 357 1087 1314 L07** indicates (b) (4)

(b) (4)

COMPLAINTS

**** These paragraphs & list REDACTION REQUIRED ****

A recent surge in consumer complaints related to Beneful dog food prompted FDA to initiate this investigation by the Coordinated Outbreak Response and Evaluation Network. This investigation simultaneously covered Nestle Purina Pet Care manufacturing plants located in OK, AZ, and PA. See **CORE FINDINGS** section.

The firm does not have a written protocol regarding consumer complaints because all consumer complaints are received and addressed by the Office of Consumer Affairs, NPPC.

The following consumer complaints regarding products manufactured by NPPC-OKC have been received by FDA (and cited by CORE) since the previous inspection:

- 115872 (8/11/2010) reported GI upset after feeding dog Beneful Healthy Weight
  Lot # 0 168 1087 1053 L06
- 116183 (8/27/2010) reported GI upset after feeding dog Purina Little Bites
  Lot #0 216 1087 0444 L04
- 128524 (10/3/2012) reported vomiting immediately after feeding Purina Cat Chow Complete
  Lot #2 235 1087 2141 L0?
- 128537 (8/15/2012) reported diarrhea after feeding Purina Kitten chow
  Lot #2 180 1087 2046 L02
- 131052 (2/6/2013) reported GI upset after feeding dog Beneful Original
  Lot #2 363 1087 1904 L02

In addition, a complaint about Lot # 2 357 1087 1314 L07 of Beneful Original was also received (and included in the list of implicated lots cited by CORE). See **CORE FINDINGS** section. ****

*****

When asked whether or not complaints had been received regarding the Beneful dog food products, Mr. (b) (6) stated that he receives a monthly report that has been compiled by NPPC, which categorizes the complaints as to issue, i.e., taste, texture, odor, etc. He stated that neither he nor anyone at the plant level has direct contact with consumers; all complaints are received and addressed by the Office of Consumer Affairs at NPPC. Mr. (b) (6) reviews the monthly report with production management and team leaders; the review process includes explanation of situations that caused a product to be placed on "hold" or notations that were made during production, etc. He stated that some processing issues, such as clumping, may be addressed by making adjustments during the production operations; however, formulation changes are not authorized at the plant level.

Complaints are not received or investigated by the manufacturing plant based on the individual complaint that was received. We attempted to sample the products implicated in the two complaints related to the Beneful dry dog food products. Mr. (b) (6) verified that none of the Beneful Healthy Weight, manufactured during 2010 (Complaint #115872) was on hand; however, a pallet of the Beneful Original, manufactured 12/28/2012 (Complaint #131052) was located in the warehouse, and we obtained samples of the product (Sample #803078 and Sample #803081). The additional product

(Beneful Original, which was manufactured 12/22/2012) related to the complaint in the CORE directive, was also on hand during this inspection. We obtained samples of this product, as well (Sample #803077 and Sample #803082). See **SAMPLES COLLECTED** section.

Upon request, Mr. (b) (6) provided information and documentation regarding the production of the Beneful Original products, including trace-back of all ingredients used in the manufacturing of the products. See **Exhibit 10:** Ingredients lists with trace-back ledgers (brown binder).

RECALL PROCEDURES

The firm has a written protocol for recalls. Mr. (b) (6) explained that only NCCP has authority to initiate a product recall. In such an event, NCCP would notify the Plant Manager and QA Manager via telephone. Then Mr., (b) (6) would trace back all affected product to determine inventory and distribution and report back to NCCP. Then NCCP would notify the customers about the recall. Mr. (b) (6) further stated that he lot numbers and products would be sent via email (in Excel format) for verification at the plant level.

Mr. (b) (6) stated that the firm conducts recall exercises (b) (4). The firm's recall protocol directs the QA Manager to conduct recall exercises on a (b) (4) basis. Mr. (b) (6) explained that since NPPC recall exercises must cover one of seven categories, the firm actually conducts "Trace Recall" exercises approximately (b) (4). The categories that are covered are: (b) (4). The most recent "Trace Recall" exercise was 3/6/2013 and involved a promotional item that was dropped into products at the packaging step.

Mr. (b) (6) (Materials Manager) would be notified by the vendor, in the event of an ingredient recall. Then he would notify Mr. (b) (6) who would conduct the trace to determine whether the ingredient had been used, and in which product(s). QA would then place a "Hold" in the inventory system for both the ingredient and the affected product, if any, and then notify NCCP. Upon authorization from NCCP, the firm would follow the vendor's instruction regarding the ingredient, or route the affected product for destruction ((b) (4)).

Mr. (b) (6) stated that ingredients are traced-back using the production date (in the manufacturing code), internal product identification number, and production schedule (which lists the ingredients and source/invoice number, etc.). Due to the volume of products manufactured during a single run (generally (b) (4)) ingredient lot numbers may be "merged" (i.e., when the quantity of one lot number is consumed and another is activated); however, these occurrences are recorded in the automated system, accounting for the identity of all ingredients used during the production run.

The firm's product recall procedure is managed by NPPC, and Mr. (b) (6) stated that the decision to initiate a product recall lies solely with the management at NPPC. He further clarified that this facility has not produced any Purina products that have been associated with a recall.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No objectionable conditions were observed during this inspection, and no FDA 483 Inspectional Observations was issued at the conclusion of this inspection.

REFUSALS

On 3/25/2013, Mr. (b) (6) told us that the NPPC corporate policy does not allow photography during inspections. I explained that photographs would be taken for evidentiary purposes only and that photography has been deemed by the US Supreme Court to be essential to any inspection. I also suggested that the firm could take a duplicate photo, in the event that a photo was taken by FDA. Mr. (b) (6) excused himself and called NPPC; he returned to stated that he had been instructed to refuse photography during this inspection. I clarified that the firm was refusing to allow photography, and Mr. (b) (6) affirmed the refusal. I requested information regarding the firm's legal counsel, and Mr. (b) (6) provided the following information on 2/26/2013: Susan M. Denigan, Legal Department, Vice President and General Counsel, St. Louis, MO; phone number 314-982-2619.

During the close out meeting on 3/28/2013, I presented two FDA Form 463 Affidavits to Mr. Reiley. I explained that one affidavit captured information regarding the receipt and testing of corn and use of ground corn as an ingredient in products manufactured by the inspected firm, and stated that FDA had collected samples of corn and ground corn on 3/26/2013. Then I explained that the second affidavit captured information regarding the manufacture and distribution of the firm's Beneful dog food products, and stated that FDA had collected samples of the products on 3/26/2013. After consulting by telephone with Mr. Chris Cowell, Regulatory Affairs, NCCP, Mr. Reiley did not read or sign either affidavit. He stated that he had permission to sign only the FDA Form 484 Receipt for Samples pertaining to the samples collected during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Discussion with management occurred throughout this inspection. Mr. (b) (6) conducted daily update meetings, which were attended by Mr. (b) (6) and Mr. Reiley. We reviewed documentation and exchanged clarifications regarding requests for information and documentation. Mr. (b) (6) provided contact information for the NPPC legal department, regarding their refusal of photography. Upon his request, I provided the reference in the Act regarding providing review of records during an officially-initiated inspection.

On 3/28/2013, I conducted a brief closeout meeting with management. Those in attendance were: Mr. William Reiley, Plant Manager; Mr. (b) (6), QA Manager; Mr. (b) (6), Production Manager; Adam Hipko, FDA Investigator; Wendy Meyer, OK State Department of Agriculture.

I reiterated the purpose of this inspection was to follow-up on consumer complaints regarding the Beneful dog food products. I also explained that no objectionable conditions were noted during this

inspection. I explained that when objectionable conditions are observed during an inspection, an FDA Form 483, Inspectional Observations is issued, citing the conditions which require correction, and that the agency may pursue legal sanctions to assure the public's health. I further explained that in such instance, the firm could respond in writing within 15 business days. I reiterated an explanation of the FSMA "Assessment of Re-inspection and Recall User Fees" to those present.

I explained that the sample results would be forth-coming, but that I did not know exactly when the results would be delivered. Then I presented the FDA Form 463 Affidavits to Mr. Reiley, for his review and signature. See **REFUSALS** section. Then I presented the FDA 484 Receipts for Samples and Mr., Reiley signed them.

Mr. (b) (6) stated that the collection of records had required significant man-hours, and he asked why the records were requested. I explained that the regulation requires all food manufacturers to record the sources of ingredients that are used in their products, in order to trace the ingredients (i.e., the "one step back"). I also told him that for this inspection, since we had been told that the firm had not made any production or formulation changes that might have resulted in the complaints that were being investigated, that other sources had to be considered, including the manufacturers of ingredients. He asked whether the suppliers (manufacturers) would be inspected, and I told him that the FDA CORE team would make such decisions. I further told him that it is commonplace for FDA to request documentation of ingredients during any inspection.

Mr. (b) (6) asked me whether the documentation that we requested was sufficient, and I told him that the documentation he had prepared would be thoroughly reviewed and correlated to this report, and used as exhibits to this report. I also verified that this report should be routed to Mr. Reiley.

Mr. (b) (6) asked Ms. Meyer whether she required any information, and she said she did not.

I asked whether anyone present had any questions, and since they did not, I thanked them for their time and cooperation, and concluded the inspection.

SAMPLES COLLECTED

Per the CORE Assignment, samples of the implicated lots were to be obtained during this inspection; however, only two of the four implicated lots were still available for sampling. In addition, since other varieties of finished Beneful products were implicated in the complaints, samples of current lots of those varieties were also obtained. Two samples of corn were collected because corn is a (b) (4) in all products manufactured at the inspected firm. Samples were collected for analysis for microbiological, mycotoxin, and toxicology screening. See **CORE FINDINGS** section.

The following samples were collected during this inspection, and submitted to FDA Laboratories:

Sent for mycotoxin analysis		Sent for Microbiological / Toxicological analysis
803075	Whole kernel corn (from (b) (4) received 3/13/2013)	
803076	Ground corn (b) (4))	

803077	Beneful Original associated w/ complaints in CORE assignment	803082
803078	Beneful Original associated with Consumer Complaint #131052	803081
803079	Beneful Healthy Weight as directed by CORE assignment	803083
803080	Beneful Radiance as directed by CORE assignment	803084

The inspected firm elected to voluntarily destroy the on-hand supply (approximately two pallets) of the implicated lots of Beneful Original dry dog food. The firm elected to "hold" the current lots of Beneful Healthy Weight and Beneful Radiance, pending analytical results; the labs were notified. See **Exhibit 11:** Hold Sheet re: Lots of Beneful manufactured on 3/25/2013.

At the close out meeting on 3/28/2013, Mr. Reiley, Plant Manager, signed a FDA Form 484 Receipt for Samples for each of the samples we collected; however, he did not read or sign the FDA Form 463 Affidavit, regarding the collection of these samples. See **REFUSALS** section.

EXHIBITS COLLECTED

Exhibit 1: List of products manufactured since August 2012
Exhibit 2: List of Sources of Oils used in Beneful products (b) (4)
Exhibit 3: Ingredients tests (76 pages)
Exhibit 4: Finished Product Testing by QA (8 pages)
Exhibit 5: Examples of Product Labeling (2 pages)
Exhibit 6: Review Worksheet for Production Lines – All Sanitation and Weekly Tasks (4 pages)
Exhibit 7: Sanitation Records for Lines 2, 7, and 12 (19 pages)
Exhibit 8: Environmental testing results (10 pages)
Exhibit 9: Distribution Records *(white binder)*
Exhibit 10: Ingredients lists with trace-back ledgers *(brown binder)*
Exhibit 11: Hold Sheet re: Lots of Beneful manufactured on 3/25/2013

ATTACHMENTS

Attachment 1: FDA Form 482 Notice of Inspection, issued to Mr. William J. Reiley, Plant Manager on 3/25/2013 (2 pages)
Attachment 2: CORE Incident Directives re: FACTS Assignment #1504446, Inspection and Sample Collection for Canine Gastrointestinal Illnesses/Beneful Dry Dog Food (2 pages)
Attachment 3: Printed version of Consumer Complaint #131052, received by FDA on 2/6/2013
Attachment 4: FDA Form 463, Affidavit, dated 3/28/2013, regarding the collection of samples of Corn and Ground Corn on 3/26/2013 (Not read or signed by Mr. William Reiley,

Plant Manager, as directed by Mr. Chris Cowell, Regulatory Affairs, Nestle Purina Pet Care, St. Louis, MO)

Attachment 5: FDA Form 463, Affidavit, dated 3/28/2013, regarding the collection of samples of finished Beneful dog food products on 3/26/2013 (Not read or signed by Mr. William Reiley, Plant Manager, as directed by Mr. Chris Cowell, Regulatory Affairs, Nestle Purina Pet Care, St. Louis, MO)

(b) (6)

Jennifer Owens Dowdy, Lead Investigator

(b) (6)

Adam C. Hipko, Investigator