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SUMMARY (AIC)

This routine, comprehensive, current Good Manufacturing Practices (cGMP) inspection of a low-acid canned food (LACF) pet food manufacturer was initiated in response to the memo: FY'17 cGMP Animal Food Inspections, dated 02/07/2017,with the Office of Regulatory Affairs (ORA) Concurrence #: FF17012601, under eNSpect Operation ID #: 63504, for the Cincinnati District Office (CIN-DO) FY'17 workplan (WP). This memo requests the firm's operations be reviewed to determine compliance with 21 CFR §507, Subparts A, B, and F.

The previous inspection of the firm was conducted by the FDA, on 03/31/2017, and was classified as No Action Indicated (NAI). That inspection served as a follow-up inspection to the firm's voluntary Class 1 Recall, initiated 10/07/2016, in response to multiple consumer complaints (CC's) involving the inclusion of apparent white plastic foreign material in the firm's finished products. No FDA 483, "Inspectional Observations," was issued at the conclusion of that inspection, nor were there any items of discussion.

The current inspection revealed that the firm continues to conduct operations as a LACF pet food manufacturer. As a comprehensive LACF inspection of the firm was conducted by FDA, end dated10/27/2016, and classified NAI, the specific LACF regulatory requirements of 21 CFR §113

were not covered in depth during this inspection. That 10/27/2016 inspection of the firm included coverage and review of the firm's Class 1 recall activities, in addition to covering LACF manufacturing. Although no FDA 483, "Inspectional Observations," was issued to the firm at the conclusion of that inspection, the investigator reviewed the firm's ongoing pest control issues in depth while explaining the violative nature of the apparent German cockroach infestation. The firm promised correction to its pest control issues during the close of that inspection.

An FDA 483, "Inspectional Observations," (***Attachment #1***) was issued at the conclusion of the current inspection to Mr. Kevin E. Oskin, Quality Food Safety Manger, for the following deviations:

1.) Failure to inspect, segregate, or otherwise handle raw materials and ingredients used in manufacturing under conditions that will protect the animal food against contamination and minimize deterioration.
2.) Failure to take effective measures to exclude pests from your plant and protect against contamination of animal food by pests (*Discussion Item from 10/27/2016 EI*).

Mr. Oskin and Ms. Nadia L. Webster-Long, Quality and Food Safety Technologist, acknowledged our observations, but would not verbally respond to our observations with corrective action/preventative action (CAPA) or timeframes. They did, however, indicate the firm would respond in writing to the District within the 15-working day timeframe we detailed.

In addition to the deviations listed on the FDA 483, "Inspectional Observations," (***Attachment #1***), the following discussion items were reviewed:

1.) An employee was observed placing a spray hose directly on the production floor. This hose is used to rinse the inside of the product hopper prior to product being piped from the hopper to the fillers and seamers.
2.) Cleaning procedures utilized during production and sanitation should be documented when additional cleaning activities are performed.
3.) Pictures sent to the sanitation manager by the pest control company's service technician should be maintained as part of the firm's pest control records.

Discussion item #1 was addressed by Ms. Webster-Long and Mr. Oskin when the deviation was observed. Ms. Webster-Long instructed the maintenance staff to change out the hose end; however, the hose itself was not observed to have been cleaned and sanitized. Mr. Oskin and Ms. Webster-Long indicated they would consider corrections to discussion items #2 & #3, but did not verbally commit to any corrections or timeframes.

The following refusals were encountered during the course of our inspection:

1.) Refusal to permit photography.
2.) Refusal to permit the review of consumer complaints.
3.) Refusal to provide photocopies of consumer complaints, manufacturing, shipping, and pest control records.

An FDA 463a, "Affidavit," (***Attachment #2***) was prepared for, and presented to, Mr. Oskin, to document interstate (IS) commerce and to cover the firm's operations including pest control. Mr. Oskin affirmed the information contained therein was true and correct to the best of his knowledge; however, he refused to sign the FDA 463a, "Affidavit," (***Attachment #2***) citing corporate policy. An additional FDA 463a, "Affidavit," (***Attachment #3***) was prepared for, and presented to, Ms. Webster-Long, to document IS commerce, to cover consumer complaints, and to cover the firm's operations. Ms. Webster-Long affirmed the information contained therein was true and correct to the best of her knowledge; however, she refused to sign the FDA 463a, "Affidavit," (***Attachment #3***) citing corporate policy.

No samples were collected during the course of the current inspection. The Official Establishment Inventory (OEI) was reviewed and updated as warranted to reflect the current operations at the firm. Changes made to the OEI included updating the points of contact.

(b) (3) (A) The firm's Food Facility Registration (FFR) was found to be active in FURLS as mandated by the Food Safety Modernization Act (FSMA); and FSMA informational handouts were provided. The firm's Federal Canning Establishment (FCE) registration and associated listings were found to be active and accurate. Preventative Controls (PC) Rule, the Final Rule for the Sanitary Transport of Human and Animal Food, and the Final Rule for the Foreign Supplier Verification Act informational handouts were provided and explained. The new provisions of FSMA, including bi-annual registration and re-inspection fees, were explained. We explained discussion items, FDA 483, "Inspectional Observations," NAI, Voluntary Action Indicated (VAI), and Official Action Indicated (OAI) inspectional classifications. Warning letters (WL), the provisions of consent decrees of permanent injunction, regulatory meetings, and respective response timeframes were detailed.

ADMINISTRATIVE DATA (AIC)

Inspected firm:	Mars Petcare US, Inc.
Location:	5115 Fisher Rd Columbus, OH 43228-9146
Phone:	614-878-7241
FAX:	614-878-6479
Mailing address:	5115 Fisher Rd Columbus, OH 43228-9146
Dates of inspection:	7/11/2017-7/14/2017 , 7/26/2017
Days in the facility:	5
Participants:	**Andrew I Carr, Lead Investigator** **Mary B Sheets, Investigator**

On 07/11/2017, we presented our credentials and issued an FDA 482, "Notice of Inspection," (***Attachment #4***) to Mr. Kevin E. Oskin, Quality Food Safety Manager, who identified himself as the most responsible person at the firm at the time of our inspection. Mr. Oskin and Ms. Webster-Long reported Mr. Gary Nicholson, Site Director, is the most responsible individual at the firm; however, he was unavailable during the current inspection.

On 07/26/2017, we presented our credentials and issued an additional FDA 482, "Notice of Inspection," (***Attachment #5***) to Mr. Oskin.

Two FDA 463a, "Affidavit," (***Attachments #2 & #3***) were prepared for, and affirmed true by, Mr. Kevin E. Oskin, Quality Food Safety Manager, and Ms. Nadia L. Webster-Long, Quality and Safety Food Technologist; however, neither signed their respective FDA 463a, "Affidavit," citing corporate policy.

An FDA 483, "Inspectional Observations," (***Attachment #1***) was issued at the conclusion of the current inspection to Mr. Kevin E. Oskin, Quality Food Safety Manger.

This establishment inspection report (EIR) was written by Investigators Andrew I. Carr and Mary B. Sheets. Initials following each section heading indicate which investigator composed that particular section.

HISTORY (MBS & AIC)

The firm continues to conduct operations as a LACF pet food manufacturer incorporated in the State of Delaware on 09/27/1995. The firm's global corporate headquarters (CHQ) are located in Brussels, Belgium, while the North American CHQ for pet care products remains in Franklin, TN. This site is comprised of approximately (b) (4) square feet under roof and located on (b) (4), as reported by Ms. Webster-Long. The firm has an estimated FDA establishment size of (b) (4) on the FDA numerical scale for gross annual sales with respect to FDA-regulated products manufactured and distributed IS.

The firm employs approximately (b) (4) staff consisting of (b) (4) administrative and (b) (4) production staff. The firm conducts operations (b) (4) Ms. Webster-Long presented us with organizational charts which depicted the administrative structure and corporate hierarchy of both the global and local corporation; however, the charts did not include specific names, only titles.

(b) (3) (A) . The firm's FFR was found to be active in FURLS as mandated by FSMA, and the firm's FCE and related listings were reviewed.

An Untitled Letter, dated 10/27/2009, was issued to the firm for concerns surrounding the firm's thermal processing.

The firm initiated a voluntary, Class 1 Recall, on10/07/2016, in response to multiple consumer complaints involving the inclusion of apparent white plastic foreign material in the firm's finished products.

All post inspectional correspondence, including the FMD-145 letter, should be addressed to:

Mr. Gary Nicholson, Site Director
Mars Petcare US, Inc.
5115 Fisher Road
Columbus, Ohio 43228

INTERSTATE (IS) COMMERCE (MBS & AIC)

Ms. Webster-Long reported 100% of the products manufactured by the firm are distributed wholesale, and approximately (b)(4)% of those products are shipped in IS commerce to consignees outside of the state of Ohio. Approximately (b)(4)% of the firm's total manufactured products are shipped to consignees outside of the United States.

Ms. Webster-Long reported approximately (b)(4)% of the firm's raw materials (RM) are received from suppliers outside of the state of Ohio. The following businesses supply bovine organ RMs to the firm:

Bovine Lung Supplier:

1.) (b) (4)

Bovine Spleen Suppliers:

1.) (b) (4)
2.) (b) (4)
3.) (b) (4)

Bovine Gullet Suppliers:

1.) (b) (4)
2.) (b) (4)
3.) (b) (4)
4.) (b) (4)

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED) (AIC & MBS)

The firm conduct operations as a LACF pet food manufacturer that distributes thermally processed wet dog and cat food in IS commerce. As such, the firm is subject to applicable FDA laws, rules, and regulations.

The firm markets dog and cat foods under the following brands/trade names:

- Pedigree®
- Cesar®
- Whiskas®
- Nutro™
- IAMS™

Representative labeling for "Pedigree® Chopped Ground Dinner with Chicken," a product being manufactured at the time of our inspection, was collected and included in the EIR as ***Exhibit #2***.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (MBS)

Mr. Mark Johnson, President:
Mr. Johnson is the regional president of Pet Nutrition in North America and is the most responsible individual for Mars Petcare US, Inc. Mr. Johnson is located at the corporate office in Franklin, TN, and did not participate in the current inspection.

Mr. Gary Nicholson, Site Director:
Mr. Nicholson is the most responsible individual at the firm on a routine basis. He was not available at the time of our inspection and did not participate. His responsibilities remain unchanged as reported in the previous comprehensive EIR, dated 10/27/2016.

Mr. Stephen M. Block, Production Manager:
Mr. Block oversees production and operations personnel and reports to Mr. Nicholson. He was not available at the time of our inspection and did not participate. His responsibilities remain unchanged as reported in the previous comprehensive EIR, dated 10/27/2016.

Mr. James S. Barritt, Government and Regulatory Manager:
Mr. Barritt works at the Franklin, TN CHQ and oversees regulatory aspects of the firm. Mr. Barritt only participated via telephone during the close-out of the current inspection on 07/26/2017.

Mr. Kevin E. Oskin, Quality Food Safety Manager:
Mr. Oskin identified himself as the most responsible individual available at the firm during the inspection and was present every day. He reported his position is regional and he reports to Ms. Peta Cutts, Quality Food Safety Director, Franklin, TN. He further reported he has held his position for seven months and has been at the firm for five years. He stated that he is responsible for the quality

and food safety of all products manufactured at the firm, and he is the only Preventative Controls Qualified Individual (PCQI) at the firm. According to Mr. Oskin, he is part of the hiring process and part of a team that develops standard operating procedures (SOP's). He further stated he does not have purchasing power or budgetary authority. The entire quality and food safety team reports to Mr. Oskin.

Ms. Nadia L. Webster-Long, Quality and Food Safety Technologist:
Ms. Webster-Long was present throughout the entire inspection. She reported she is a member of the Quality and Food Safety team, has held her current position for over ten years, and has been with the firm for thirteen years. According to Ms. Webster-Long her responsibilities focus on training, regulatory, complaints, product grading, incident management, and the support of research and development activities for tubs and pouches. She stated she has no hiring, firing, or budgetary authority. Ms. Webster-Long led each day of the inspection and refused our requests for photocopies of documents citing corporate policy and instruction from the firm's regulatory department. She maintained primary contact with the regulatory department in Franklin, TN throughout the inspection. After each request for complaint logs and photocopies of documents, Ms. Webster-Long replied that either the regulatory team was not available, or the team refused the request. These numerous requests, delays in responses, and subsequent refusals delayed the completion of the inspection until 07/26/2017. Ms. Webster-Long led each of our walk-throughs of the manufacturing area, while often denying complete access to all areas of the firm. Most notably, Ms. Webster-Long appeared to intentionally avoid lines (b) (4) of the firm when we requested to observe those specific areas.

Ms. Rachel M. Valinsky, Quality and Food Safety Technologist:
Ms. Valinsky stated she is a member of the Quality and Food Safety team and has held her current position with the firm for seven years. Ms. Valinsky reported she oversees the firm's software system and has updated programs since the last inspection. Ms. Valinsky is Ms. Webster-Long's back-up for training, regulatory matters, and high risk chemical ingredients. Ms. Valinsky reports to Mr. Oskin.

Ms. Katie R. Kennedy, Quality and Food Safety Technologist:
Ms. Kennedy reported she is a member of the Quality and Food Safety team and has been in her current position for one year. Ms. Kennedy previously worked at the Mars Petcare US, Inc., Washington Courthouse, OH, site for three years. Ms. Kennedy reports to Mr. Oskin and stated she took over most of the cannery operations from Ms. Valinsky. Ms. Kennedy further described her other responsibilities to include back-up for consumer complaint investigations, corrective action preventative action, and internal audits. Mr. Oskin identified Ms. Kennedy as a "jack-of-all-trades" at the firm.

Mr. David E. Smyers, Continuous Improvement Manager:
Mr. Smyers reported he has been with the company for approximately 16.5 years, and in his current position for 4.5 years. Mr. Smyers stated he is also the firm's Food Safety team leader and works "hand-in-hand" with Mr. Oskin. Mr. Smyers further reported he and Mr. Oskin manage a budget, but can spend up to $50,000 outside of the budget, as needed. Mr. Smyers stated he assists with the

hiring process, rolling out new quality requirements, pest control, and sanitation. In addition, Mr. Smyers reported he is responsible for the training of employees in quality, calibration, change management, and quality holds. Mr. Smyers reports to Gary Nicholson, Site Director.

Mr. Robert G. Casteel, Sanitation Manager:
Mr. Casteel has been with the firm for three months and is largely responsible for the firm's sanitation and pest control programs. He oversees all sanitation activities and grants approval for production to resume after the (b) (4). Mr. Casteel stated that after the operators clean, sanitize, initial, and date the sanitation logs, he inspects the zones and scores the condition of the zones to indicate their level of acceptance. In regards to pest control, Mr. Casteel reviews (b) (4) pest control reports generated (b) (4) after (b) (4) visits. He is responsible for addressing and implementing sanitation and pest control recommendations. Mr. Casteel actively participated in the inspection facilitating our review of the firm's Pest Control Reports and employee Pest Sighting Logs.

Mr. Joshua M. Basil, Health Safety Environment Manager:
Mr. Basil spoke to us on the first day of the inspection to address and review the firm's visitor safety guidelines with us.

(b) (6), Thermal Process Technologist:
(b) (6) has been with the firm for (b) (6). He is one of (b) (4) Thermal Process Technologists at the firm who are responsible for receiving and assessing thermal process deviations. (b) (6) attended Thermal Process Control School and has training in Deviation Analysis, Heat Penetration Testing, and Temperature Distributions.

(b) (4), Thermal Process Technologist:
(b) (4) is one of (b) (4) Thermal Process Technologists at the firm and shares responsibility for receiving and assessing thermal process deviations.

(b) (4), Calibration Technician:
(b) (4) has been with the firm for (b) (4) and reports to (b) (4). He stated that he is responsible for greater than (b) (4) quality equipment calibrations and received OJT to perform his duties. (b) (4) reported he is involved with (b) (4) documents and batch review.

(b) (4), Quality and Food Safety Technologist:
(b) (4) works in the Analytical Laboratory and performs testing on in-process raw product that has not been thermally processed. (b) (4) lead our walk-through of the laboratory which included explaining the functions of each instrument and detailing her job duties.

Mr. Richard Shawn Ellis, Inbound Logistics Manager:
Mr. Ellis participated in the inspection, on 07/26/2017, where he discussed the acquisition of RMs, IS shipment of finished product, and provided bill of ladings for our review.

FIRM'S TRAINING PROGRAM (MBS)

The firm adheres to the training regimen defined by corporate. Training is offered in both a classroom setting and as on-the-job trainings. Ms. Webster-Long explained the firm uses a training platform, (b) (4) to track training and to provide consistency, ease of use, and to allow all employees to receive the same information. (b) (4) Ms. Webster-Long explained the employees use the remote to record attendance, watch the presentations, and answer quiz questions. If a passing score is not reached, management works with the employee to ensure understanding and successful completion. Ms. Webster-Long stated all employees receive (b) (4) different trainings every period; approximately every (b) (4) . The same (b) (4) topics are covered with varying related subjects. The fixed topics are Associate Communication Meeting (ACM), Health and Safety Environment (HSE), and Quality and Food Safety (QFS). If training is not completed each (b) (4) (b) (4) automatically notifies management. Management receives an incentive bonus for (b) (4) training completion, and is therefore motivated to ensure all training is completed. We reviewed the following training documents and no issues were encountered.

- "2017 Period Training Sessions"
- "HACCP Essential Level Training"
- "HACCP Advanced Level Training"
- "(b) (4) , TP-036 Rev 8"
- "(b) (4) , WI-01856 Rev 2"

MANUFACTURING/DESIGN OPERATIONS (AIC & MBS)

The current inspection revealed the firm continues to conduct operations as a LACF pet food manufacturer that distributes wet dog and cat food in thermally processed cans, semi-rigid plastic containers ("Tubs"), and laminated pouches. There have been no significant changes to the firm's manufacturing operations or processes since the last NAI, comprehensive LACF inspection, conducted on 10/27/2016. The specific LACF regulatory requirements of 21 CFR §113 were not covered in depth during this inspection, as this inspection focused on the cGMP requirements of 21 CFR §507, Subparts A, B, and F.

The firm has (b) (4) manufacturing lines each with different fillers based on product consistency and final product packaging. Manufacturing equipment remains as reported in the previous EIR, dated 10/27/2016, with the exception of modifications to the (b) (4) pet food lines. These lines now include (b) (4) to improve the natural look of the formed chunks. In addition, all (b) (4) lines have been updated and are now equipped with (b) (4). (b) (4) are present on the (b) (4) lines, while (b) (4) are now utilized on the (b) (4) lines.

Sanitation:

No environmental swabs or aerobic plate counts (APC's) of the environment are performed by the firm. Mr. Robert Casteel, Sanitation Manager, reported cleaning and sanitation of the manufacturing area is conducted (b) (4) . All lines stop and are cleaned with (b) (4) depending on the line/area. The (b) (4) used is (b) (4) The sanitizing agent used is "(b) (4) ." We reviewed Sanitation SOP, "WI-01666 Rev 2" for (b) (4) , which contained the following steps:

1.) (b) (4)

Mr. Casteel briefly summarized the cleaning and sanitizing steps as:

- (b) (4)

During our inspection and review of the firm's manufacturing SOP's and batching records, on 07/13/2017, we requested to observe any cleaning &/or sanitization activities performed by the firm during the typical production day, or between, per se, different recipes. Ms. Webster-Long reported the firm had already switched over to the recipe they would be running the remainder of the day, and no further in-process cleaning would occur for the remainder of the shift. We subsequently requested to again walk-through the manufacturing, warehousing, and laboratory areas of the firm. During this walk-through of the manufacturing area, on 07/13/2017, we observed an employee spray rinsing out the inside of a product hopper used to hold product prior to it being piped to the fillers. After spray rinsing the hopper, the employee dropped the spray hose onto the production floor instead of placing it back onto the spray hose storage reel, and continued about his cleaning activities (*Please see Discussion Item #1 in the General Discussion with Management section of this report for further information*).

Investigator Carr asked Ms. Webster-Long, and then Mr. Oskin, if it was common practice for employees to drop spray hoses and related equipment directly onto the production floor while continuing to perform cleaning and manufacturing activities. Ms. Webster-Long and Mr. Oskin indicated this was not common practice, and the employee would be retrained in acceptable cGMPs. Ms. Webster-Long immediately requested maintenance to change-out the hose end explaining it takes a special tool to change-out the hose ends, which we observed. We did not, however, observe the cleaning and/or sanitizing of the hose that extends into the hopper as the employee reaches his arm into the product hopper to spray rinse the product hopper. This observation was not included on the FDA 483, "Inspectional Observations," (***Attachment #1***) issued to Mr. Oskin during the close of the current inspection; however, it was reviewed during the close-out as a discussion item.

We reviewed (b) (4) sanitation log, (b) (4) Swab Record, 07457 Rev 7," with review date 7/10/2017. (b) (4) swabbing indicates the presence of organic material; and if organic material is still

present after first cleaning, re-cleaning is necessary followed by re-testing. Additionally, we reviewed, "(b) (4) Sanitation Sign Off, 04288 Rev 11," dated 07/03/2017, 06/26/2017, 06/19/2017, and 06/12/2017, where operators initialed and dated the log. Mr. Casteel reported the operators who clean each area approve or disapprove the cleanliness of the area prior to initiating production. In addition to the operator's initials, Mr. Casteel scores the zones (b) (4) with number (b) (4) (b) (4) where only number (b) (4) being acceptable. The "(b) (4) Sanitation Sign Off, 04288 Rev 11," had scores of (b) (and (b) (4) without corrective actions listed. Mr. Casteel explained if he scores a (b) (4) the operators re-clean the area and he then re-scores; however, this is not documented on the production record, nor is the score (b) (4) then changed to (b) (4) Investigator Carr informed the firm if re-cleaning and subsequent re-scoring of production equipment/the production environment is performed by the firm, these activities should be recorded on the firm's production/sanitation records so these activities are documented. Mr. Casteel agreed and indicated he would research recording these activities on the firm's production/sanitation records (*Please see Discussion Item #2 in the General Discussion with Management section of this report for further information*).

Pest Control:

Ms. Webster-Long and Mr. Oskin reported the firm contracts with (b) (4)) for (b) (4) pest control services. Services provided include interior rodent traps, exterior rodent bait stations, interior insect light traps (with glue board), (b) (4) and as-needed chemical treatments and the identification of, and suggested repairs for, areas of ingress and egress as observed during (b) (4) visits. (b) (4) also now provides fumigation and related targeted services on an as-needed basis. Mr. Casteel explained typically (b) (4) pest control operators (PCO) visit every (b) (4) (b) (4) Mr. Casteel continued the PCO's sometimes return the following day if there are concerns or if additional pest control services &/or measures are warranted or requested. The firm maintains all (b) (4) "Pest Control Reports" electronically within the software program utilized and provided to the firm by (b) (4) Mr. Casteel demonstrated the software program and related reports to us via his notebook computer during the course of the inspection.

During the previous comprehensive LACF inspection, dated 10/27/2016, the investigator reviewed the firm's pest control deviations – most notably the firm's German cockroach infestation (which is most prominent on production lines (b) (4)) – in-depth with management during the course of the inspection and during the close-out. The firm indicated appropriate measures (b) (4)) would be researched and implemented to remedy its German cockroach infestation. The current inspection, however, revealed the firm has only recently begun the aforementioned pest control measures.

Ms. Webster-Long stated (b) (4) now visits (b) (4) to combat the roaches, but Mr. Casteel corrected her and stated the visits are still (b) (4) . Mr. Casteel continued to explain (b) (4) has started coming at night when roaches are most active. Upon our review of the electronic "Pest Control Reports," Investigator Sheets noted an entry for a night time pest control visit, on 06/27/2017, with a time in of "9:59pm" and a time out of "11:45pm."

Mr. Casteel and Mr. Oskin reported the firm is now employing the services of an entomologist to evaluate the German cockroach infestation and implement a treatment regiment to eradicate them from the firm. (b) (4) Mr. Casteel reported these efforts have only recently begun; however, he believes there has been somewhat of a decrease in cockroach activity.

During our review of the electronic pest control reports with Mr. Casteel, we noted the PCO's indicated they sent pictures of pest activity, disrepair of dock doors, general disrepair of the building, areas of ingress and egress, excessive spills of RM, and damaged cans "covered" in flies, to Mr. Casteel. Mr. Casteel reported the PCO's do send pictures to his phone during each visit; however, these pictures are not maintained or added to the firm's pest control records. Investigator Carr informed the firm the pictures sent to Mr. Casteel by the PCO's should be maintained as part of the firm's pest control records. Mr. Casteel agreed and indicated he would research how to include the pictures in his pest control records (*Please see Discussion Item #3 in the General Discussion with Management section of this report for further information*).

During our review of the PCO's reports, we observed instances where requests/suggestions for repairs, &/or significant pest activity in the same areas, were reported to the firm at the end of multiple visits. For example: Damage to dock door (b) (4) was reported to the firm on multiple consecutive visits. The PCO's reports appeared to indicate the damage to dock door (b) (4) was first reported on or about 09/26/2016, and then reported again during each (b) (4) visit until the repairs were completed, on or about 11/03/2016. The damage was reported during the 10/03/2016 visit, where Ms. Webster-Long indicated dock door (b) (4) was assigned the status of "planned work." She continued an actual work order to make the repairs was created on or about 11/01/2016, and the dock door was repaired on or about 11/03/2016. I (Investigator Carr) inquired if it was typical for repairs to dock doors to take that long before repairs are made when the PCO's have made repeated requests to have the area of ingress repaired. Ms. Webster-Long reported the firm sometimes delays repairs until they have a few that can all be included on the same work order. Mr. Oskin further reported the firm must also sometimes wait for parts. I (Investigator Carr) indicated my concern with areas of ingress &/or general disrepair of the firm remaining unrepaired and open for an extended period of time where pests have immediate access to the building. No additional responses were provided by the firm.

On 07/13/2017, during our walk-through of the firm, we observed a live, apparent German cockroach in the (b) (4) " of the manufacturing area of the firm. This area is adjacent to the "(b) (4) , where in-process raw material and ingredients are maintained. On 07/13/2017, we observed an additional live, apparent German cockroach near the main hand-wash station at the entrance to the manufacturing area of the firm (*Please see Observation #2 in the Objectionable Conditions & Management's Response section of this report for further information*).

We reviewed the firm's "Pest Sighting Log" that is used by employees to record the visual sightings of pests, date/time, pest concern, person reporting, location, action taken, and when concern was addressed and by whom. The PCO's follow-up on this log during their (b) (4) visits and initial and date the log when they perform their follow-up on each entry. Our review of the firm's employee pest sighting log, and the pest control reports left by (b) (4) PCO's, revealed even with increased PCO visits/treatments and assistance from an entomologist, a significant German cockroach infestation of the firm persists.

Our multiple requests for photocopies of the firm's employee "Pest Sighting Log," as well as the "Pest Control Reports" generated by the (b) (4) PCO's at the end of each service visit, were refused by Mr. Oskin and Ms. Webster-Long. As such, we recorded the information from the logs into our regulatory notebooks for inclusion within this EIR. The handwritten entries made by the firm's employees on the employee "Pest Sighting Log," for the period of 11/02/2017 to 11/17/2017, were entered into the table below for ease of review.

Date	Pest	Location	Comment(s) from Employee	Date Addressed by PCO	Days Taken to Address
11/02/2016	Multiple Roaches	(b) (4)		11/07/2017	5
11/10/2016	Roach	(b) (4)	Got Away	11/14/2017	4
11/10/2016	Roaches	(b) (4)		11/14/2017	4
11/11/2016	Roach	(b) (4)		11/14/2017	3
11/16/2016	Roaches	(b) (4)	Killed What Could, Lots	11/21/2017	5
11/18/2016	Roaches	(b) (4)		11/21/2017	3
11/21/2017	Roach	(b) (4)		11/24/2017	3
11/30/2017	Roach	(b) (4)		12/09/2017	9
12/05/2017	Roach	(b) (4)		12/19/2017	14
12/05/2017	Roach	(b) (4)		12/09/2017	4
12/05/2017	Roach	(b) (4)		12/19/2017	14
12/07/2017	Spiderwebs	(b) (4)		12/09/2017	2
12/13/2017	Roaches	(b) (4)	Millions of Roaches	12/27/2017	14
12/14/2017	Spiderwebs	(b) (4)		12/27/2017	13
12/14/2017	Roach	(b) (4)		12/27/2017	13
12/16/2017	Roach	(b) (4)		12/27/2017	11
12/16/2017	Roaches	(b) (4)		12/27/2017	11
12/30/2017	Roaches,Bugs	(b) (4)	Many Roaches & Other Bugs	01/09/2017	9

Date	Pest	Location	Comment(s) from Employee	Date Addressed by PCO	Days Taken to Address
12/30/2017	Roaches	(b) (4)		01/09/2017	9
01/03/2017	Roach	(b) (4)		01/09/2017	6
01/03/2017	Roach	(b) (4)		01/09/2017	6
01/09/2017	Roach	(b) (4)		01/09/2017	<1
01/12/2017	Roach	(b) (4)		01/16/2017	4
01/15/2017	Roach	(b) (4)		01/16/2017	1
01/16/2017	Roach	(b) (4)		01/16/2017	<1
01/27/2017	Roaches	(b) (4)		01/30/2017	3
01/30/2017	Multiple Flies	(b) (4)		01/30/2017	<1
01/31/2017	Roach	(b) (4)		02/06/2017	6
02/01/2017	Roach	(b) (4)		02/06/2017	5
02/06/2017	Roaches, Larvae	(b) (4)	Multiple Roaches & Larvae	02/06/2017	<1
02/08/2017	Roach	(b) (4)		02/13/2017	5
02/13/2017	Roach	(b) (4)		02/15/2017	2
02/20/2017	Roach	(b) (4)		02/20/2017	<1
02/20/2017	Maggots	(b) (4)		02/20/2017	<1
02/22/2017	Roaches	(b) (4)		02/27/2017	5
02/27/2017	Roach	(b) (4)		02/27/2017	<1
02/27/2017	Roach	(b) (4)		02/27/2017	<1
03/01/2017	Roach	(b) (4)		03/06/2017	5
03/03/2017	Roach	(b) (4)		03/06/2017	3
03/06/2017	Roach	(b) (4)		03/06/2017	<1
03/06/2017	Roaches	(b) (4)		03/06/2017	<1
03/06/2017	Roaches	(b) (4)		03/06/2017	<1
03/06/2017	Roaches & Larvae	(b) (4)		03/06/2017	<1
03/08/2017	Roaches	(b) (4)		blank	Unknown
03/13/2017	Roaches	(b) (4)		blank	Unknown
03/13/2017	Roaches	(b) (4)		blank	Unknown
03/14/2017	Mouse	(b) (4)		blank	Unknown
03/14/2017	Roaches	(b) (4)		blank	Unknown

Date	Pest	Location	Comment(s) from Employee	Date Addressed by PCO	Days Taken to Address
03/15/2017	Roaches	(b) (4)		blank	Unknown
03/15/2017	Roach	(b) (4)		03/27/2017	12
03/17/2017	Roaches	(b) (4)		03/27/2017	10
03/17/2017	Roaches	(b) (4)		03/27/2017	10
03/18/2017	Invasion of Roaches	(b) (4)	Invasion of Roaches	03/27/2017	9
03/22/2017	Roach	(b) (4)		03/27/2017	5
03/22/2017	Roach Infestation	(b) (4)	Roach Infestation	03/27/2017	5
03/24/2017	Roach	(b) (4)		03/27/2017	3
03/27/2017	Roach	(b) (4)		03/27/2017	<1
03/27/2017	Multiple Roaches	(b) (4)	Multiple Roaches	03/27/2017	<1
03/29/2017	Roach	(b) (4)		blank	Unknown
03/29/2017	Multiple Roaches	(b) (4)	Multiple Roaches	blank	Unknown
03/31/2017	Roach	(b) (4)		blank	Unknown
03/31/2017	Roach Infestation	(b) (4)	Roach Infestation	blank	Unknown
04/03/2017	Roach Infestation	(b) (4)	Roach Infestation	blank	Unknown
04/03/2017	Roaches	(b) (4)		blank	Unknown
04/03/2017	Roach	(b) (4)		blank	Unknown
(b) (4)					
04/21/2017	*Illegible*	(b) (4)		05/01/2017	10
04/21/2017	Roach	(b) (4)		05/01/2017	10
04/21/2017	Roaches	(b) (4)		05/01/2017	10
04/21/2017	Fly	(b) (4)		05/01/2017	10
04/24/2017	Roaches	(b) (4)		05/01/2017	7
04/26/2017	Roaches	(b) (4)		05/01/2017	5

Date	Pest	Location	Comment(s) from Employee	Date Addressed by PCO	Days Taken to Address
04/27/2017	Roaches	(b) (4)		05/01/2017	4
04/28/2017	Roaches	(b) (4)		05/01/2017	3
04/28/2017	Roach	(b) (4)		05/01/2017	3
05/01/2017	Roaches	(b) (4)		05/01/2017	<1
05/03/2017	Roaches & Spiders	(b) (4)		05/08/2017	5
05/08/2017	Roach	(b) (4)		05/08/2017	<1
05/10/2017	Roaches	(b) (4)		05/15/2017	5
05/11/2017	Roaches	(b) (4)	Everywhere	05/15/2017	4
05/12/2017	Roaches	(b) (4)		05/15/2017	3
05/13/2017	Roaches	(b) (4)		05/15/2017	2
05/15/2017	Roaches & Spiders	(b) (4)		05/15/2017	<1
05/15/2017	Roaches	(b) (4)		05/30/2017	15
05/15/2017	Dead Flies	(b) (4)		05/30/2017	15
05/15/2017	Beetles	(b) (4)		05/30/2017	15
05/17/2017	Roaches	(b) (4)		05/30/2017	13
05/17/2017	Roach	(b) (4)		05/30/2017	13
05/19/2017	Roach	(b) (4)		05/30/2017	11
05/19/2017	Fly	(b) (4)		05/30/2017	11
05/22/2017	Roach	(b) (4)		05/30/2017	8
05/22/2017	Roach	(b) (4)		05/30/2017	8
05/24/2017	Multiple Roaches	(b) (4)	Multiple Roaches	05/30/2017	6
05/24/2017	Roach Infestation	(b) (4)	Roach Infestation	05/30/2017	6
05/24/2017	Bird	(b) (4)		05/30/2017	6
05/25/2017	Roaches	(b) (4)		05/30/2017	5
05/26/2017	Bird	(b) (4)		06/12/2017	17
06/02/2017	Roach	(b) (4)		06/12/2017	10
06/02/2017	Roach	(b) (4)		06/12/2017	10
06/07/2017	Roach	(b) (4)		06/12/2017	5
06/12/2017	Bugs/Roach	(b) (4)		06/12/2017	<1

Date	Pest	Location	Comment(s) from Employee	Date Addressed by PCO	Days Taken to Address
06/12/2017	Roaches	(b) (4)		06/12/2017	<1
06/12/2017	Roaches	(b) (4)		06/12/2017	<1
06/16/2017	Roaches	(b) (4)		06/19/2017	3
06/21/2017	Roaches	(b) (4)		06/26/2017	5
06/30/2017	Roach	(b) (4)		07/10/2017	10
07/05/2017	A lot of Roaches	(b) (4)	A lot of Roaches	07/10/2017	5
07/13/2017	Roaches	(b) (4)		NA	
07/13/2017	Roaches	(b) (4)		NA	
07/14/2017	Roaches	(b) (4)		NA	
07/13/2017	Roaches	(b) (4)	Mr. Oskin reported roaches seen on our 07/13 walk through.	NA	

Table #1 – Mars Petcare US, Inc., Employee Pest Sighting Log

Calibrations:

Mr. Scott Chambers, Calibration Technician, oversees more than (b) (4) quality calibrations (b) (4) . Mr. Chambers reported, on 07/12/17, he performs spot-checks throughout the year to assess instrument/equipment calibrations; however, when asked to supply record of these checks, he stated that he did not actually do spot-checks. Mr. Chambers further explained he relies on employees to alert him of issues with instrument/equipment calibrations. Once identified as requiring calibration, the instrument/equipment is/are sent to the vendor for repair &/or calibration. For larger equipment, Mr. Chambers reported the vendor performs the calibration or repair(s) on site, while also indicating the firm maintains spares to use while instruments/equipment are being repaired &/or calibrated.

The following calibrations were reviewed by Investigator Sheets and revealed no deviations:

1.) "(b) (4) steam domes" by (b) (4)
2.) "(b) (4) cooling tower"
3.) "(b) (4) discharge leg"
4.) "(b) (4) feed leg"
5.) "(b) (4) Instrumentation Calibrations"
    a. Digital temperature gauge
    b. HMI temperature recorder
    c. Pressure indicator
    d. Pressure recorder

e. Air flow transmitter
f. Chart recorder time
g. Speed of fan

6.) "(b) (4) Software Version 7.03a"
7.) "(b) (4) gauge"

MANUFACTURING CODES (MBS)

Manufacturing codes remain unchanged from the previous comprehensive EIR, dated 10/26/2016.

COMPLAINTS (MBS & AIC)

Ms. Webster-Long explained Mars Consumer Care Division in Franklin, TN, handles all in-bound consumer complaints. As such, the firm does not always see each consumer complaint received unless the Consumer Care Team in Franklin, TN, is able to verify the product was manufactured at the Columbus, OH location, and believes there is enough merit in the complaint to warrant an investigation. Ms. Webster-Long explained the firm classifies consumer complaints on a numerical scale (b) (4) . A Level (b) (4) complaint contains very limited information and typically no product lot number or identifying information. These complaints contain so little information the manufacturing site cannot routinely be determined. As complaints become more reliable and detailed, they increase numerically up to Level (b) (4) for those complaints that contain all needed information to identify the manufacturing site, while also possessing enough merit to warrant an inspection.

Ms. Webster-Long explained the Consumer Care Team in Franklin, TN, forwards consumer complaint investigations (CCI) to Mr. Oskin, Ms. Webster-Long, and Ms. Kennedy as a "PRIMP" (Product Related Incident Management Process). Ms. Webster-Long stated she receives the PRIMP and starts an investigation. When the investigation is complete, a suggestion is sent back to the Consumer Care Team in Franklin, TN, who follows up with the consumer. Ms. Webster-Long further explained if a CAPA is warranted based on the findings of her investigation, it is created by Mr. Smyers, Continuous Improvement Manager. Additionally, Ms. Webster-Long explained PRIMP trends are monitored to identify any trends which would indicate an increase in consumer complaints for any one particular issue (e.g., dented cans, FO's, pets presenting with illnesses following consumption, etc.).

On 07/13/2017, Ms. Webster-Long reported this site routinely receives approximately (b) (4) complaints (b) (4) from Consumer Care Team in Franklin, TN. Additionally, Ms. Webster-Long reported if consumer complaints are received directly at this site, they are forwarded to the Consumer Care Team. When we requested to review the firm's site-specific consumer complaint log documenting these complaints received directly by the firm, Ms. Webster-Long contended no such log or record of said complaints are maintained at the Columbus, OH, location.

On 07/14/2017, following our repeated requests to review the firm's consumer complaints – specifically those complaints involving the inclusion of FO's in the firm's finished products – Ms.

Webster-Long reported the Consumer Care Team in Franklin, TN, agreed to share their top three consumer complaint categories with us.

The consumer complaints shared covered only those received in May 2017; covered only complaints received for their Pedigree canned "loaf" dog foods manufactured at this site; covered only those complaints classified as "Level (b)(4) complaints; and covered only those complaints received in the firm's top three most frequently received consumer complaints categories presented to us by Ms. Webster-Long as follows:

1. Packaging, damaged or dented
   - (19 Consumer Complaints Received)
2. Growth of mould (mold)
   - (14 Consumer Complaints Received)
3. Low meat/excess gravy or gel
   - (7 Consumer Complaints Received)

Ms. Webster-Long presented these complaints to us via bar chart projected onto the whiteboard in the firm's conference room we utilized during this inspection. Upon the presentation of these complaints, Investigator Carr informed the firm these consumer complaints are considered "quality" complaints, and we had requested repeatedly those consumer complaints involving the inclusion of FO's in the firm's finished products. Ms. Webster-Long indicated the firm had not received any consumer complaints involving the white, plastic FO's that were the concern for their previous, formal Class I Recall, initiated 10/07/2016. Investigator Carr then asked if the firm had received other consumer complaints involving any plastics or other FO's in the firm's product. Ms. Webster-Long and Mr. Oskin reported the firm had not received any consumer complaints involving the white, plastic FO's that were the concern for their previous, formal Class I Recall, initiated 10/07/2016 (*For additional information, please see Observation #1 in the Objectionable Conditions & Management's Response section of this report. Additionally, the two FDA 463a, "Affidavit," (**Attachments #2 & #3**) prepared for, and affirmed true by, Mr. Kevin E. Oskin, Quality Food Safety Manager, and Ms. Nadia L. Webster-Long, Quality and Safety Food Technologist, dated 07/26/2017, detail further information regarding the inclusion of plastic FO's in the firm's finished products*).

During the inspection, we presented the firm with 13 consumer complaints reported to FDA, from 05/02/2016 to the present. After reviewing the information already available to Ms. Webster-Long; she confirmed she was aware of seven of the 13 consumer complaints FDA had received regarding products the firm manufactures. Of these seven consumer complaints, two involved white, plastic FO's in the firm's finished product; although Ms. Webster-Long and Mr. Oskin reported several times when questioned the firm had not received additional consumer complaints regarding white, plastic FO's in the product they manufacture since they closed their investigation into the recall referenced above. (*For additional information, please see Observation #1 in the Objectionable Conditions & Management's Response section of this report).*

For ease of review, these 13 consumer complaints received by FDA were compiled into a table and included within the EIR as ***Attachment #6***.

RECALL PROCEDURES (MBS & AIC)

Ms. Webster-Long and Mr. Oskin stated there were no open recalls at the time of this inspection. The firm's previous formal, Class I recall, dated 10/07/2016, involved (b) (4) (b) (4) – as determined by the firm – contained within the firm's: "CESAR Classics Filet Mignon Flavor," wet dog food packaged in tubs (semi-rigid plastic containers). According to Ms. Webster-Long, the recall has been closed out, although she could not provide a date of closure. Mr. Oskin stated the root cause was determined to be the presence of white, (b) (4) plastic FO's contained within the firm's inbound ingredients received from beef suppliers. He explained the following three CAPA's have been initiated.

1.) Increase inbound inspection
2.) Increase finished product inspection
3.) Increase audit of inbound suppliers

On 07/13/2017, Mr. Oskin and Ms. Webster-Long again explained the firm's prevention strategy had the following four actions that have always been performed, but are now performed more frequently:

1.) Spot checks of frozen meats with a "(b) (4) that separates the meat for examination
2.) Inspections at filling
3.) Packaging inspections by opening cans on line every (b) (4) after sterilization
4.) Daily Assessment Panel (DAP) looks (b) (4) container per (b) (4) per (b) (4) after it is on a pallet

On 07/11/2017, Mr. Oskin stated the firm has not had any additional reports of white plastic FO's in the firm's finished product. He continued there have been no additional consumer complaints involving white plastic FO's since initiating the aforementioned preventative actions. However, as indicated above in the Complaints section of this EIR, two of the 13 consumer complaints we reviewed with the firm involved white, plastic FO's in the firm's finished product which Ms. Webster-Long verified the firm was aware of (*For additional information, please see Observation #1 in the Objectionable Conditions & Management's Response section of this report).*

During the directed, recall follow-up inspection of the firm, dated 03/31/2017, the firm indicated all CAPAs had been implemented; however, our inspection of the firm revealed the firm had not yet fully implemented each CAPA. The 03/31/2017 EIR's section titled, "Mars Site Corrective Actions," states the firm changed all food contact white plastic (b) (4)) to a blue (b) (4) plastic. Mr. Oskin reported using only (b) (4) plastic in/on the firm's equipment would permit the firm to easily identify whether future inclusions of (b) (4) plastics in finished product originated from the firm or from one of the firm's suppliers. However,

on 07/11/2017, Mr. Oskin stated only the "majority" of belts and plastic wear plates in/on critical equipment had been changed out to the (b) (4) plastics.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (AIC)

Observations Listed on form FDA 483, "Inspectional Observations:"

Observation #1:

You did not inspect, segregate, or otherwise handle raw materials and ingredients used in manufacturing under conditions that will protect the animal food against contamination and minimize deterioration.

1. On 07/14/2017, your Quality and Food Safety Technologist stated plastic (b) (4) are often contained within the frozen bovine tissues (raw material) received by your firm. These bovine tissues are utilized in the finished dog and cat foods manufactured and distributed into interstate (IS) commerce by your firm.

    a. Your Quality and Food Safety Technologist reported when plastic foreign objects (FO) are not removed from the frozen bovine tissues during their visual inspection, these plastic FOs can be incorporated into the finished dog and cat foods manufactured and distributed into IS by your firm.

    b. Your firm initiated a formal recall, on 10/07/2016, in response to the presence of plastic FOs in the finished dog and cat foods manufactured and distributed into IS by your firm.

    c. Your Quality and Food Safety Technologist further reported your firm has received additional consumer complaints involving plastic FOs discovered in the finished dog foods manufactured and distributed into IS by your firm.

Reference:
21 CFR §507.25(b)(1)

Supporting Evidence and Relevance:

The firm continues to receive complaints involving FO inclusion in their finished products. The presence of any FOs in finished product offered for sale and introduced into IS commerce is a significant food safety risk, while also constituting a regulatory violation. This inclusion of FO's including, but not limited to, plastics in the firm's finished product is a recurrent issue.

Ms. Webster-Long stated, while Mr. Oskin corroborated, the firm is aware their incoming (b) (4) (b) (4) utilized in the manufacture of many of the firm's products, often contains plastic FO's. Ms. Webster-Long and Mr. Oskin explained they are aware of the presence of (b) (4) in their incoming (b) (4) where they are most often included in the (b) (4) of (b) (4) . (b) (4) are plastic (b) (4)) devices (b) (4) (b) (4) to prevent (b) (4) (b) (4) Ms. Webster-Long indicated a visual inspection of this (b) (4) is performed prior to the (b) (4) entering the grinder for processing; however, this visual inspection is largely inadequate, as plastic FO's continue to be included in the firm's finished products. Please see the two FDA 463a, "Affidavit," (***Attachments #2 & #3***) prepared for, and affirmed true by, Mr. Kevin E. Oskin, Quality Food Safety Manager, and Ms. Nadia L. Webster-Long, Quality and Safety Food Technologist, dated 07/26/2017, for further information regarding the inclusion of plastic FO's in the firm's finished products.

The firm initiated a formal, Class 1 Recall, on 10/07/2016, in response to the presence of plastic FOs in the finished dog and cat foods manufactured and distributed into IS by the firm. Ms. Webster-Long and Mr. Oskin reported the firm successfully closed this recall hypothesizing the white plastic discovered in their finished product originated from (b) (4) supplied to the firm by several (b) (4) . Ms. Webster-Long and Mr. Oskin further reported they disqualified some of thei (b) (4) suppliers following the firm's investigation into the recall, while also increasing their visual inspection of these (b) (4) however, the inclusion of plastic FO's in the firm's finished products continues to occur.

During the inspection, we requested information from the firm for a consumer complaint received by FDA, on or about 11/06/2016, involving white plastic in the firm's product. When questioned, Ms. Webster-Long reported the firm had also received this complaint and she initiated a formal PRIMP. The complainant reported the FO was of a white, pull tab-like piece of plastic found in Cesar Classic brand wet dog food. Ms. Webster-long indicated the firm sent out a package to the consumer to collect the suspect product and FO, which she did receive back. Ms. Webster-Long reported her investigation revealed that the chunk of plastic appeared to be a piece of (b) (4) . Ms. Webster-Long again reported these (b) (4) are often included in the (b) (4) the firm receives from (b) (4) . Mr. Oskin and Ms. Webster reported all recipes for all loaf products manufactured by the firm (b) (4) .

On a number of instances during the inspection, we requested to review the consumer complaints the firm had received involving plastic FO's in their finished products. Ms. Webster-Long reported the firm does not receive consumer complaints directly, and no log of complaints is maintained at their site. Ms. Webster-Long and Mr. Oskin stated, on several occasion, the firm had not received any complaints regarding plastic FO's in the firm's finished product related to their previous Class I Recall.

On 07/14/2017, Ms. Webster-Long stated she received approval from the firm's Consumer Care Team in Franklin, TN, to share the top three complaint categories for canned pet foods from May 2017. The complaint information presented only covered what are considered to be product

"Quality" related consumer complaints. The following three categories of consumer complaints received by the firm in May, 2017, were presented via PowerPoint: 1.) Dented cans, 2.) "Mould" on product (which is the gravy that surrounds loaf products misidentified by consumers – not actual mold), and 3.) Not enough meat in product.

During the inspection, we presented the firm with 13 consumer complaints reported to FDA, from 05/02/2016 to the present. After reviewing the information already available to Ms. Webster-Long; she confirmed she was aware of seven of the 13 consumer complaints FDA had received regarding products the firm manufactures and distributes. Of these seven consumer complaints, two involved white, plastic FO's discovered in the firm's finished product which Ms. Webster-Long reported the firm was aware of. Prior to this, Ms. Webster-Long and Mr. Oskin reported several times when questioned the firm had not received additional consumer complaints regarding white, plastic FO's in the product they manufacture since they closed their investigation into the recall referenced above.

Discussion with Management:

The severity of our observations, and the significant danger the inclusion of plastics – or any other FO's – poses to the public health of animals was reviewed in depth with the firm. Ms. Webster-Long and Mr. Oskin acknowledged our observations; however, no corrective actions or timeframes were given upon our request. Ms. Webster-Long and Mr. Oskin indicated the firm would respond in writing to the District to our observations.

It was discussed with Ms. Webster-Long and Mr. Oskin the complaint information presented for our review during the inspection were what are consider to be "Quality" complaints and not the type of complaints we were requesting to review.

Repeated verbal requests were made for the firm to share information they had regarding any FO's – plastic or otherwise – the firm may have received. Ms. Webster-Long and Mr. Oskin refused to provide complaint information for FO inclusion in finished product, or complaints regarding adverse reactions occurring following exposure to the firm's products.

It was reiterated several times during the inspection the firm needs to share information requested by FDA during inspections. Refusing to provide requested records and information for review prevents FDA investigators from being able to thoroughly evaluate the firm's manufacturing processes to ensure the safety of the firm's products and determine compliance with applicable FDA law, rules, and regulations.

Observation Correction Status:
Not Corrected

OBSERVATION #2:

You did not take effective measures to exclude pests from your plant and protect against contamination of animal food by pests.

Specifically,

1. On 07/13/2017, during our walk-through of your firm, we observed a live, apparent German cockroach in the (b) (4) " of the manufacturing area of your firm. This area is adjacent to the "(b) (4) , where in-process raw material and ingredients are maintained.

2. On 07/13/2017, during our walk-through of your firm, we observed a live, apparent German cockroach near the main hand-wash station at the entrance to the manufacturing area of your firm.

3. On 07/11-14/2017, and again on 07/26/2017, during our review of your Employee Pest Sighting Log, we observed the following recorded instances of pest activity in the manufacturing, warehouse, silo, boiler/mechanical rooms, and related areas of your firm.

    a. From 11/10/2016 to 07/14/2017, there were approximately 72 days where your employees recorded approximately 99 instances of German cockroach sightings/activity in primarily the manufacturing areas of your firm. Your employees recorded sighting between one up to "Millions of Roaches."

    b. Your pest control service technician recorded sighting from 12 up to 250 roaches during visits to your firm on 06/26/2017, 06/27/2017, and 07/03/2017. These sightings were recorded for lines (b) (4) & (b) (4) as well as surrounding manufacturing and warehouse areas of your firm.

    c. From 11/10/2016 to 07/14/2017, your employees recorded approximately eight instances of fly, maggot, spider, and beetle sightings/activity in the manufacturing and warehousing areas of your firm.

    d. From 11/10/2016 to 07/14/2017, your employees recorded approximately two instances of bird sightings/activity in the manufacturing and warehousing areas of your firm.

Reference:
21 CFR §507.19(e)

Supporting Evidence and Relevance:

The failure to take adequate measure to exclude and prevent pests from the manufacturing and related areas of the firm poses a significant public health safety concern while also being a regulatory violation. The firm was warned about the seriousness of their German cockroach infestation during the previous comprehensive inspection, dated 10/27/2016. During that inspection, the firm promised to explore additional ways of eradicating the established population of German cockroaches infesting the firm; however, the firm only recently began utilizing the services of an entomologist to assess their infestation, rotating chemicals, and additional treatments at night.

The magnitude of the firm's ongoing pest infestation – most notably apparent German cockroaches – is exhibited above in the Employee Pest Sighting Log we recorded from the firm's original pest control records during the inspection for inclusion in this EIR. Ms. Webster-Long indicated we were free to review the firm's pest control and related records and record the information we required; however, she refused our multiple request for photocopies of these records citing corporate policy.

Ms. Webster-Long and Mr. Oskin reported all of the firm's loaf products packaged in tubs are manufactured on lines (b) (4) & (b) (4) The above Employee Pest Sighting Log exhibits the severity of the apparent German cockroach infestation as reported by the firm's employees and the firm's PCO. There were approximately 45 employee sightings of apparent German roaches on the immediate areas of lines (b) (4) & (b) (4); with more sightings in close proximity to lines (b) (4) & (b) (4). Additionally, Ms. Webster-Long confirmed the firm has received consumer complaints regarding the inclusion of insects in the firm's finished product.

Please see the two FDA 463a, "Affidavit," (***Attachments #2 & #3***) prepared for, and affirmed true by, Mr. Kevin E. Oskin, Quality Food Safety Manager, and Ms. Nadia L. Webster-Long, Quality and Safety Food Technologist, dated 07/26/2017, for further information regarding the firm's ongoing pest control issues and refusals to provide photocopies of records.

Discussion with Management:

The severity of our observations as related to filth and the failure to take adequate measures to exclude pests from the manufacturing and related areas of the firm was reviewed in depth. Ms. Webster-Long and Mr. Oskin acknowledged our observations; however, no corrective actions or timeframes were given upon our request. Ms. Webster-Long and Mr. Oskin indicated the firm would respond in writing to the District to our observations.

It was reiterated several times during the inspection the firm needs to share information requested by FDA during inspections. Refusing to provide requested records and information for review prevents FDA investigators from being able to thoroughly evaluate the firm's manufacturing processes to ensure the safety of the firm's products and determine compliance with applicable FDA law, rules, and regulations.

Observation Correction Status:
Not Corrected

REFUSALS (AIC)

The following refusals were encountered during the course of our inspection:

1.) Refusal to permit photography.
2.) Refusal to permit the review of consumer complaints.
3.) Refusal to provide photocopies of consumer complaints, manufacturing, shipping, and pest control records.

GENERAL DISCUSSION WITH MANAGEMENT (AIC)

Representing the firm, and present for the close of the current inspection, were the following individuals:

- Mr. Kevin E. Oskin, Quality Food Safety Manager
- Ms. Nadia L. Webster-Long, Quality and Food Safety Technologist
- Ms. Rachel M. Valinsky, Quality and Food Safety Technologist

while LCDR Mary B. Sheets, Investigator, and I (Andrew I. Carr, Investigator) represented FDA. Additionally, and joining during the close of the inspection, Mr. James S. Barritt, Government and Regulatory Manager, participated via conference phone.

An FDA 463a, "Affidavit," (***Attachment #2***) was prepared for, and presented to, Mr. Oskin, to document IS commerce and to cover the firm's operations including pest control. Mr. Oskin affirmed the information contained therein was true and correct to the best of his knowledge; however, he refused to sign the FDA 463a, "Affidavit," (***Attachment #2***) citing corporate policy. An additional FDA 463a, "Affidavit," (***Attachment #3***) was prepared for, and presented to, Ms. Webster-Long, to document IS commerce, to cover consumer complaints, and to cover the firm's operations. Ms. Webster-Long affirmed the information contained therein was true and correct to the best of her knowledge; however, she refused to sign the FDA 463a, "Affidavit," (***Attachment #3***) citing corporate policy. Following their respective refusals to sign the FDA 463a, "Affidavit," (***Attachment #2 & #3***), I (Investigator Carr) denoted the refusals to sign within the body of each document.

An FDA 483, "Inspectional Observations," (***Attachment #1***) was then issued to Mr. Kevin E. Oskin, Quality Food Safety Manger, for the following deviations:

1.) Failure to inspect, segregate, or otherwise handle raw materials and ingredients used in manufacturing under conditions that will protect the animal food against contamination and minimize deterioration.

2.) Failure to take effective measures to exclude pests from your plant and protect against contamination of animal food by pests.

Mr. Oskin and Ms. Webster-Long acknowledged our observations, but would not verbally respond to our observations with CAPAs or timeframes. They did, however, indicate the firm would respond in writing to the District within the 15-working day timeframe we detailed.

In addition to the deviations listed on the FDA 483, "Inspectional Observations," (***Attachment #1***), the following discussion items were reviewed:

1.) An employee was observed placing a spray hose directly on the production floor. This hose is used to rinse the inside of the product hopper prior to product being piped from the hopper to the fillers and seamers.
2.) Cleaning procedures utilized during production and sanitation should be documented when additional cleaning activities are performed.
3.) Pictures sent to the sanitation manager by the pest control company's service technician should be maintained as part of the firm's pest control records.

Discussion item #1 was addressed by Ms. Webster-Long and Mr. Oskin when the deviation was observed. Ms. Webster-Long instructed the maintenance staff to change out the hose end; however, the hose itself was not observed to have been cleaned and sanitized. Mr. Oskin and Ms. Webster-Long indicated they would consider corrections to discussion items #2 & #3, but did not verbally commit to any corrections or timeframes.

The following refusals were encountered during the course of our inspection:

1.) Refusal to permit photography.
2.) Refusal to permit the review of consumer complaints.
3.) Refusal to provide photocopies of consumer complaints, manufacturing, shipping, and pest control records.

Repeated verbal requests were made for the firm to share any information they might have received involving FO's – plastic or otherwise – in the products they manufactured and distributed in IS. Ms. Webster-Long and Mr. Oskin contended the firm had no such information, and refused to provide any consumer complaint information for FO inclusion in their distributed finished products, or complaints received regarding any adverse reactions which might have occurred following exposure to the firm's products. These requests were made for consumer complaints that were in addition to the 13 FDA received and we reviewed with them.

It was reiterated several times during the inspection the firm needs to share information requested by FDA during inspections. Refusing to provide requested records and information for review prevents FDA investigators from being able to thoroughly evaluate the firm's manufacturing processes to ensure the safety of the firm's products and determine compliance with applicable FDA law, rules, and regulations.

The PC Rule, the Final Rule for the Sanitary Transport of Human and Animal Food, and the Final Rule for the Foreign Supplier Verification Act informational handouts were provided and explained. The new provisions of FSMA, including bi-annual registration and re-inspection fees, were explained. We explained discussion items, FDA 483, "Inspectional Observations," NAI, VAI, and OAI inspectional classifications. WL's, the provisions of consent decrees of permanent injunction, regulatory meetings, and respective response timeframes were detailed.

We then asked if there were any questions from those present during the close-out, to which they responded no, and the inspection concluded.

SAMPLES COLLECTED (AIC)

No samples were collected during the course of this inspection.

VOLUNTARY CORRECTIONS (AIC)

No FDA 483, "Inspectional Observations," was issued, and no discussion items were addressed, at the conclusion of the previous inspection, dated 03/31/2017. As such, there were no CARS/OCAR data to enter into eNSpect. The discussion item regarding pest control issues addressed at the conclusion of the previous comprehensive, LACF inspection, dated 10/27/2016, was not found to be corrected during this inspection. As such, this discussion item was listed on the FDA 483, "Inspectional Observations," (***Attachment #1***) issued to Mr. Oskin at the close of this inspection.

EXHIBITS COLLECTED (AIC)

Exhibit #1:	(b) (4) ," dated 05/31/2017.	(3 pgs)
Exhibit #2:	Representative labeling for "Pedigree® Chopped Ground Dinner with Chicken"	(3 pgs)

ATTACHMENTS (AIC)

Attachment #1:	FDA 483, "Inspectional Observations," issued to Mr. Kevin E. Oskin, Quality Food Safety Manager, dated 07/26/2017.	(3 pgs)
Attachment #2:	FDA 463a, "Affidavit," unsigned by Mr. Kevin E. Oskin, Quality Food Safety Manager, dated 07/26/2017.	(3 pgs)
Attachment #3:	FDA 463a, "Affidavit," unsigned by Ms. Nadia L.Webster-Long, Quality and Safety Food Technologist; dated 07/26/2017.	(3 pgs)
Attachment #4:	FDA 482, "Notice of Inspection," issued to Mr. Kevin E. Oskin, Quality Food Safety Manager, dated 07/11/2017.	(3 pgs)
Attachment #5:	FDA 482, "Notice of Inspection," issued to Mr. Kevin E. Oskin, Quality Food Safety Manager, dated 07/26/2017.	(3 pgs)

Attachment #6: 13 Consumer Complaints received by FDA for this firm. (1 pg)

x Andrew I. Carr -S
Digitally signed by Andrew I. Carr -S
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Andrew I. Carr
Investigator

x Mary B. Sheets -S2
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Date: 2017.08.30 10:06:13 -04'00'

Mary B. Sheets
Investigator