

CGMP ANIMAL FOOD INSPECTION REPORT

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| FEI/CFN: 3010836469 | DATE(S) INSPECTED: 3/8, 3/9 & 3/11/21 | INSPECTOR(S): Lead Inspector- Doreen Mausbach, Denver Alsup, Stan Cook, Ethan Willis and State insp. Madison Fink | |
| BUSINESS NAME: Heartland Pet Food Manufacturing | | STREET ADDRESS: 8101 E. 32 nd . Street | |
| | | MAILING ADDRESS: Same | |
| TOWN/ CITY: Joplin | STATE: MO. | ZIP: 64804 | PHONE: 417-952-1400 |
| EMAIL: dsolcz@bluebuff.com | FIRM'S WEBSITE: | | FAX: |

SUMMARY OF FINDINGS

This was a Full Scope PCAF 21 CFR 507 CGMP/PC Surveillance inspection performed by assignment under contract HHSF223201810204C Virtually on 3/8/2021 and 3/9/2021 by the Missouri Department of Agriculture. Lead Inspector Doreen E. Mausbach was accompanied by Denver Alsup, Stan Cook, Ethan Willis all FDA credentialed Inspectors and State inspector Madison Fink. Follow up walk through, inspection of further records, grounds and close out was conducted on 3/11/2021 by lead inspector Doreen E. Mausbach, Denver Alsup and State inspector Madison Fink.

The most responsible person at Heartland Pet Food Manufacturing is Dana Solcz-Quality Engineer. Ms. Solcz was lead information provider during this inspection. A 482-Notice of Inspection, Preventive Control for Animal Food, and Sanitary Transportation of Human and Animal Food Factsheets were electronically transmitted to Ms. Solcz prior to virtual meeting. FDA credentials and State credentials were presented at beginning of virtual meeting on 3/8/21 and again upon arrival at plant on 3/11/21. Also present from Heartland Pet Food was Kevin Fuller-Production Manager, Greg Burnham-Corporate Food Manager, Michael Burkhart-Production Manager, Mike Schulz-Plant Manager, Tammy Hogan-Senior Quality Manager, Joshua Messer-Quality Supervisor, Keesa Bennett-Assistant FSQ manager and Scott Ayton-Operations manager.

There were no refusals during this inspection. The current inspection covered the receipt of ingredients, production and distribution facilities related to the production involving four separate processes including extrusion dry kibble pet food, pet treat injection molding, pet treat drying process, and a dry pet treat extrusion process This inspection included a complete review of the food safety plan, training records, hazard analysis through virtual correspondence. An on-site inspection included a review of receiving and distribution records, walkthrough of the grounds, plant, receiving and distribution facilities related to the production and distribution of those products manufactured at the facility.

This plant is a manufacturer of dry kibble pet food and pet treats for dogs and cats. Firm's office is open Monday-Friday 8-5; manufacturing hours are (b) (4) with (b) (4) employees. Firm manufacturers approximately (b) (4) pounds of non-medicated bagged products annually. PM materials are handled at this location. Firm receives 85-90% ingredients from out of state suppliers and approximately 90% out of state distribution with less than 10% of product going to Canada and

Mexico. There is storage for approximately (b) (4) tons of bulk storage. Incoming ingredients come in bulk, tote, and liquid or bagged form.

Hazard analysis was looked at in Food Safety Plan, firm relies on Supply Chain for some controls, and firm provided Certifications from third party verifiers along with audit forms. Firm utilizes SOPs for GMPs to control some hazards. All records (training, personnel, supporting documents, etc.) were made available for review.

Firm has Assays on hand from Missouri Department of Agriculture sampling of products, State will continue to follow up with Assays.

Complaints were addressed at this inspection (see complaint section below).

No 483 observations were noted during this Inspection

During close-out meeting management was warned of their responsibility to be in compliance with the F, D, & C Act and failure to do so could result in seizure, injunction, criminal, or civil penalties.

HISTORY

The most recent inspection at this facility was a BSE inspection performed under contract on 06/05/2019 and was classified as NAI.

The firm is owned by General Mills Food, MN. As of April 2018.

Firm has no regulatory or legal issues pending, has 235 employees. The firm operates 24/7.

The firm's food facility registration is current as of October 15, 2020.

INTERSTATE (I.S.) COMMERCE

Firm receives 85-90% ingredients from out of state suppliers; Brown Rice-Arkansas; Fish meal-Texas; Potatoes-Illinois and imported products such as frozen lamb from New Zealand and frozen duck from France. Firm has approximately 90% out of state distribution with less than 10% of product going to Canada and Mexico.

JURISDICTION (Products Manufactured and/or Distributed)

The establishment manufactures, processes, or holds animal food for sale in the United States and is subject to 21 CFR Part 507. This location produces non-medicated dry kibble pet food and pet treats for Blue Buffalo Pet Foods. Product may have prohibited material in it.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The most responsible person at Heartland Pet Food Manufacturing is Dana Solcz-Quality Engineer. Ms. Solcz was lead provider with the information during this inspection. 482-notice of inspection, Preventive Control for Animal Food, and Sanitary Transportation of Human and Animal Food Factsheets was electronically transmitted to Ms. Solcz prior to Virtual meeting. FDA credentials and State credentials were presented at beginning of virtual meeting on 3/8/21 and again upon arrival at plant on 3/11/21. Also present from Heartland Pet Food was Kevin Fuller-Production Manager, Greg Burnham-Corporate Food Manager, Michael Burkhart-Production Manager, Mike Schulz-Plant Manager, Tammy Hogan-Senior Quality Manager, Joshua Messer-Quality Supervisor, Keesa Bennett-Assistant FSQ manager and Scott Ayton-Operations manager.

FIRM'S TRAINING PROGRAM

Firm's personnel appear to be qualified to perform their assigned duties. Records of training were complete. Training program covering animal food hygiene and animal food safety, including the importance of employee health and personal hygiene as appropriate to the animal food produced, the facility and individual assigned duties seems to have been implemented. Firm has a program in place for new hire's and then followed up with annual training for all employees.

MANUFACTURING / DESIGN OPERATIONS

Personnel

Management has a training program documented and procedures to ensure that personnel conform to hygienic practices that protect against the contamination of animal food. Records of training were in place to indicate that training is being completed. Records are kept for a minimum of two years. All training is done annually besides the new hire training package.

Plants and Grounds

The plants and grounds seem to be maintained in a manner to protect against contamination of animal food. The grass was cut with no excess growth around the buildings or equipment. Traffic areas leading up to the plant, receiving pit appeared to be draining. No evidence of pest activity was noted either around or in the buildings. Pest service by (b) (4) appears to be adequate. Records of visits and treatment by the contractor were available for viewing. Plant consists of one building surrounded by a paved parking lot. Building consist of offices, restrooms, break areas, manufacturing area for kibbles and separate manufacturing area for treats, freezers, dehy room, storage, labs, micro-room, unloading pit, liquid unloading pit, loading and unloading docks. Lighting fixtures are of the types that have shielding around them to prevent breakage or are shatter resistant. Bathrooms were provided, clean, well lit and had hot and cold running water and soap for washing hands.

Sanitation

Plant in general was kept clean and in good repair. All trash is collected and disposed of. All receptacles are color coded for their area and properly marked for trash or reused. Plant has a written SOP for Sanitation procedures in Food Safety Plan and also GMP, these are two separate SOP's.

Water Supply and Plumbing

This plant is on city water and sewage. Firm has documents on hand for viewing. Water is used in production of products. No issues have been noted.

Equipment and Utensils

Fork lifts are used for the transportation of bulk tote feed materials within the plant. Distribution of ingredients from trucks to bins is via covered unloading pits or pumping station through closed system throughout the plant.

Plant Operations

All ingredient and finished product storage is adequately identified. All inbound/outbound trucking is checked for previous load and cleanout procedures. Records and written SOP's for GMP practices are available for review.

Holding and Distribution

All inbound/outbound feed ingredients are delivered via commercial trucking. There is storage for approximately (b) (4) tons of bulk storage. Incoming ingredients come in bulk, tote, and liquid or bagged form. Bulked grain and liquid are stored in bins, bagged products are stored on storage racks in warehouse, or freezer. All incoming and outgoing products have a sample collected from it and may be tested according to FSP or GMP requirements. Firm produces (b) (4) pounds of bagged product annually. Non-Prohibited material is contracted and sold to swine farm in Tennessee for further processing. Have records of clean out material that is not salvaged going to landfill.

MANUFACTURING CODES

Firm assigns their own lot code number for each inbound product that comes into loading dock. When product is blended, another number is generated. All finished product has a lot number attached.

COMPLAINTS

Firm has procedures in place for complaints that come in. Most complaints come through corporate office, corporate office then contacts Joplin plant if a follow up investigation is needed. Followed up on 13 complaints that were filed in esaf with FDA; Five from 2016 (#144756, #144761, #145977, #148397, #147849) and two from 2017(#148437, #149088); firm is not aware of these complaints and the data is too insufficient for them to follow back into their records. Three complaints from 2019 (#158345, #161799, #158438) and two of three from 2020 (#162399, #163400) the firm stated that they could not confirm if corporate may or may not have received them, the plant itself is not aware of them, if received, corporate would have done a follow up with the plant specifically for product manufactured at the Joplin facility and a thorough investigation would have been completed. For complaint # 164441, received 09/09/2020, the corporate team did receive a similar complaint but no further action was requested by the Joplin plant.

RECALL PROCEDURES

The firm has documented recall procedures in Food Safety Plan, Mock recalls are done at least (b) (4) .

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No objectionable conditions to address in writing.

REFUSALS

There were no refusals during the course of this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Present during the closeout discussion with management were; lead inspector Doreen E. Mausbach and Denver Alsup both with FDA credentials and State inspector Madison Fink. Firm had in attendance; Dana Solcz-Quality Engineer, Michael Burkhart-Production Manager, Mike Schulz-Plant Manager, Joshua Messer-Quality Supervisor, Keesa Bennett-Assistant FSQ manager and Scott Ayton-Operations manager.

No 483 observations were issued.

ADDITIONAL INFORMATION

N/A

SAMPLES COLLECTED

No samples were collected during this inspection.

VOLUNTARY CORRECTIONS

No previous issues to address.

EXHIBITS COLLECTED

N/A

ATTACHMENTS

FDA 482

SIGNATURE

Doreen Mausbach

Inspector

A handwritten signature in black ink that reads "Doreen Mausbach". The signature is written in a cursive style with a large initial "D" and a long horizontal flourish at the end.