

Table of Contents

Summary..... 1
Administrative Data..... 2
History..... 3
Interstate Commerce 3
Jurisdiction 3
Individual Responsibility and Persons Interviewed 3
Manufacturing/Design Operations..... 4
Complaints..... 5
Refusals 5
General Discussion with Management..... 5
Samples collected 6
Exhibits Collected 6
Attachments..... 6

Summary

This directed inspection of this pet treat manufacturer was conducted as a follow up for consumer complaint numbers: 113565, 113568, 113676, 119456, and 119517. The inspection was performed as a joint inspection with the State of Missouri Department of Agriculture.

The previous inspection was conducted on 3/3/2010 for a complaint follow up to complaint #112263. No FDA 483 was issued to the firm during the previous inspection.

The current inspection revealed the firm continues to manufacture bone treats for dogs and the operations for processing and complaints were reviewed and relevant documents were obtained. After requesting initial information regarding complaints and processing, the inspection was refused on 1/10/2012 by Joseph G. Ryan, Plant Manager. The State of Missouri Department of Agriculture and I returned on 1/24/2012 to continue the inspection. No FDA 483 was issued and one sample, DOC 701242, was collected. The firm is currently registered (b)(3).

Handouts for food security, Reportable Food Registry (RFR), and the FSMA information sheet were given to Mr. David S. Frick and each item was discussed. At the conclusion of the inspection, management was warned of the firm's responsibility to adhere to the FD&C Act.

Establishment Inspection Report

Dynamic Pet Products, LLC.
Washington, MO 63090-1050

FEI: 3007001915
EI Start: 1/10/2012
EI End: 1/26/2012
SKG

Administrative Data

Inspected Firm: Dynamic Pet Products, LLC.
Address: 360 M.E. Frick Drive
Washington, MO 63090
Phone: (636) 239-2200
Fax:

Date of inspection: 1/10/2012, 1/24/2012, and 1/26/2012
Investigators: Samuel K. Gibbons, Jr., Investigator – (Present all dates during inspection)

Stan Cook, Program Administrator, Missouri Dept of Agriculture
– (Present 1/10/2012)

Ken Disselhorst, Feed, Seed and Treated Timber Inspector II, Missouri
Dept of Agriculture – (Present 1/10/2012 and 1/24/2012)

I presented my credentials and issued the FDA 482, Notice of Inspection, to Joseph G. Ryan, Plant Manager, on 1/10/2012. The Missouri Department of Agriculture officials did not sign the FDA 482, and showed their own non-FDA credentials. A 2nd FDA 482, Notice of Inspection, was issued to Dave Frick, President, on 1/24/2012, and credentials were shown upon arrival to continue the inspection after the previous refusal by Joseph G. Ryan, Plant Manager on 1/10/2012. Ken Disselhorst was also present on 1/24/2012, however did not sign the FDA 482 and showed only Missouri Department of Agriculture credentials upon arrival.

The MO Department of Agriculture reviewed similar processes and complaints during this inspection, and also discussed the firm’s palatability studies with management. The agency will write a separate report for this establishment inspection.

(b) (5)
(b) (5)
(b) (5) During the inspection, I requested to speak with the USDA agent in the plant; however, Mr. Joseph G. Ryan insisted he would let them know the FDA was at the facility.

Handouts for food security, Reportable Food Registry (RFR), and the FSMA information sheet were given to Mr. David S. Frick and each item was discussed.

Establishment Inspection Report

Dynamic Pet Products, LLC.
Washington, MO 63090-1050

FEI: 3007001915

EI Start: 1/10/2012

EI End: 1/26/2012

SKG

History

Dynamic Pet Products, LLC, is owned by Frick's Quality Meats which has been in business since approximately 1986. Dynamic Pet Products has been producing the real ham bones since 2001, and it and the jumbo pork femur bone are the only pet products produced at this facility.

Hours of operation are (b) (4). The firm is currently registered (b)(3).

The FMD-145 letter and any post inspectional correspondence should be addressed to the firm's president at:

Mr. David S. Frick
Dynamic Pet Products, LLC.
360 M.E. Frick Drive
Washington, MO 63090

Interstate Commerce

The firm receives its pork bones from (b) (4) and ships its finished products to various stores across the United States. DOC 701242 shows the movement of raw ingredients and finished product in interstate commerce.

Jurisdiction

FDA regulates the retail and wholesale of animal food products such as the bone treats intended for dogs produced by this firm. Raw pork bones are received, processed, and sold through this firm.

Individual Responsibility and Persons Interviewed

David S. Frick, President, is the most responsible individual at this firm. He has been with the company approximately 30 years and is responsible for developing and implementing the annual plan of operation. Mr. Frick has the authority to hire and fire employees and I observed Mr. Frick directing employees during the inspection. Mr. Frick was available for 1/24/2012 and 1/26/2012 during this inspection.

Joseph G. Ryan, Plant Manager, provided us with the general tour in the facility and briefly described the processing procedures for the bone treats. The first FDA 482, Notice of Inspection, was issued to Mr. Ryan on 1/10/2012 due to the absence of David S. Frick. After a

Establishment Inspection Report

Dynamic Pet Products, LLC.
Washington, MO 63090-1050

FEI: 3007001915
EI Start: 1/10/2012
EI End: 1/26/2012
SKG

brief tour of the facility and minimal information gathering, Mr. Ryan refused to continue the inspection on 1/10/2012. He reports to David S. Frick, President.

Sara K. Frick-Mades, Director of Plant Services, was also present for the inspection and answered questions relating to complaints. Mrs. Frick-Mades also provided relevant documents and information regarding shipping and receiving of products.

Rebecca Guzy, Director, Food Safety and Product Development, was present for the inspection and provided information regarding processing of the bone treats.

Stan Cook, Program Administrator for the Missouri Department of Agriculture, accompanied me for the 1st day, 1/10/2012, of this inspection as part of a joint inspection. Also with the Missouri Department of Agriculture, **Ken Disselhorst, Feed Seed and Treated Timber Inspector II**, was present for 1/10/2012 and 1/24/2012.

Manufacturing/Design Operations

The production process previously reported during the 3/3/2012 inspection was incorrect as stated by management during this inspection. Management stated the information during the last inspection was relayed incorrectly to the FDA. The same process is used for both the Jumbo Pork Femur and the Real Ham Bone products. The correct process is as follows:

The firm receives the pork femur bones (sow and market hog) containing small amounts of meat left on the bone. The bones are carried via conveyor through a (b) (4) coloring. The bones take approximately (b) (4) to pass through the (b) (4) where they are then treated with dry granular ingredients: (b) (4) (b) (4). The bones are next placed (b) (4) approximately (b) (4) bones per netting and are (b) (4) where the (b) (4) as follows:

(b) (4) F – (b) (4)

(b) (4) F – (b) (4) hours

(b) (4) F – an average of (b) (4) (time varies due to internal temperature probe of bones reaching (b) (4) F)

After smoking the bones, the bones enter a (b) (4) of (b) (4) F for at least (b) (4). After cooling, the firm individually wraps each bone by vacuum packing it in plastic. A label is applied to each bone, each passes through a metal detector, and the bones are then boxed for shipment. Once packaged, the bones are kept at ambient temperature.

The firm stated they would like the processing information to be kept confidential as it considered proprietary information

Establishment Inspection Report

Dynamic Pet Products, LLC.
Washington, MO 63090-1050

FEI: 3007001915

EI Start: 1/10/2012

EI End: 1/26/2012

SKG

Complaints

Complaints since the last inspection were reviewed, and the firm continues to pay customer vet bills up to \$(b)(4) on a case by case basis. The firm will verify it was their product which initiated the complaint; however, does not look at production records as part of any investigation into the root cause. Complaints received by the firm for 2010 equaled 21 total complaints, and complaints for 2011 equaled 22 complaints. The firm stated they produced (b)(4) bones in 2010, and (b)(4) in 2011. Sara Frick-Mades provided information on overall complaints, and provided information on individual complaints received by FDA. She also provided me with a copy of the firm's complaint form that is used when a complaint is received (See Exhibit 1). I followed up on the following FDA consumer complaints: 113565, 113568, 113676, 119456, and 119517. The firm did not have information on complaint #113676, and Mrs. Frick-Mades stated she called but could not reach the consumer for #119517. Complaints 113565 and 114568 both (b)(4); (b)(6) and 119456 stated (b)(4); (b)(6) (b)(4); (b)(6) David S. Frick stated due to complaints he has looked into updating a label with more warnings and bolder statements, and also stated the firm has begun to think of only producing the Jumbo bones to have a larger and stronger product, but no decision has been made regarding either option.

Refusals

On 1/10/2012, after a brief tour of the facility and minimal information regarding complaints and processing was obtained, Joseph G. Ryan, Plant Manager, refused to continue the inspection until the FDA provided a statute, case, or law proving FDA had jurisdiction over dog bone treats. I read Mr. Ryan section 704(a)(1) of the FD&C Act as well of the definition of a food as considered by FDA; however, he did disagreed and stated dog bones are not food. Mr. Ryan also stated he wanted to postpone the inspection until the next week due to the owner, David S. Frick, being away from the facility. Mr. Ryan was told this act would be considered a refusal by FDA, prior to myself and the Missouri Department of Agriculture officials being escorted out of the facility.

General Discussion with Management

Handouts for food security, Reportable Food Registry (RFR), and the FSMA information sheet were given to Mr. David S. Frick and each item was discussed. At the conclusion of the inspection, Mr. Frick was warned of the firm's responsibility to adhere to the FD&C Act.

Establishment Inspection Report

Dynamic Pet Products, LLC.
Washington, MO 63090-1050

FEI: 3007001915

EI Start: 1/10/2012

EI End: 1/26/2012

SKG

Samples collected

DOC 701242 was collected to document interstate commerce of (b) (4) cases of Dynamic Pet Products Real Ham Bone which were produced at Dynamic Pet Products, LLC, 360 M.E. Frick Drive, Washington, MO 63090. The sample includes:


- 1) Unsigned affidavit, 1 page
- 2) (b) (4) Bill of lading # (b) (4) 2 pages
- 3) Dynamic Pet Products, LLC computer printout, dated 1/24/2012, 1 page
- 4) Dynamic Pet Products, LLC Sales order inquiry computer printout, dated 11/14/2012, 2 pages
- 5) Frick's Quality Meats (Dynamic Pet Products, LLC) Bill of lading # (b) (4) 1, 2 pages
- 6) Representative labeling for Dynamic Pet Products, LLC Real Ham Bone, 1 page

Exhibits Collected

- 1) Complaint form example

Attachments

- 1) FDA 482 – Notice of Inspection, Issued to Joseph G. Ryan, Plant Manager, on 1/10/2012.
- 2) FDA 482 – Notice of Inspection, Issued to Dave Frick, President, on 1/24/2012.



Samuel K. Gibbons, Jr., Investigator