SUMMARY OF FINDINGS

A for-cause inspection of this pet food manufacturer was initiated per the request of CVM in reference to adulterated beef tallow containing pentobarbital that was distributed by (b) (4), received by the firm. This inspection was identified as MARCS Op ID: 96033.

This inspection was conducted in accordance with 21 CFR part 507 for firm's subject to the PCAF regulation, including small firms with fewer than 500 full-time equivalent employees. This inspection did not cover 21 CFR part 507, subparts C, *Hazard Analysis and Risk-Based Preventive Controls*, or E, *Supply Chain Program*. Coverage included a walk-thru of the firm's receiving, manufacturing, and finished product storage areas. The firm's incoming shipping records for beef tallow, complaint files, recall procedures, sanitation procedures, and distribution records were also reviewed during the current inspection. The firm was manufacturing Orijen Original, Acana Heritage Palo, and Acana Lamb & Apple Treats during the current inspection. This current inspection was classified as NAI, No Action Indicated. No FDA 483, Inspectional Observations was issued.

The previous cGMP inspection was conducted on 02/07/2018 under contract by University of Kentucky Regulatory Services and was classified as NAI, No Action Indicated. No FDA 483, Inspectional Observations was issued.

(b) (3) (A) . No refusals were encountered. No reconciliation exam was performed during the current inspection.

ADMINISTRATIVE DATA

Inspected firm:	Champion Petfoods USA, Inc.
Location:	12781 Bowling Green Rd Auburn, KY 42206
Phone:	
FAX:	
Mailing address:	12781 Bowling Green Rd Auburn, KY 42206
Dates of inspection:	05/16/2018, 05/17/2018, 05/23/2018
Days in the facility:	Three (3)
Participants:	Justin N. Henson, Investigator Caitlin L. Almonrode, Investigator

Post-inspectional FDA correspondence including FDA-145 correspondence should be addressed to:

Champion Petfoods USA, Inc.
Amanda C. Flowers, Quality Assurance Manager
12781 Bowling Green Rd.
Auburn, KY 42206
aflowers@championpetfoods.com

On 5/16/2018, Investigator Caitlin L. Almonrode and I arrived at Champion Petfoods USA, Inc., 12781 Bowling Green Rd., Auburn, KY 42206 and presented credentials to Ms. Amanda C. Flowers, Quality Assurance Manager, (b)(6) & (b)(7)(c), Sanitation Team Lead, (b)(6) & (b)(7)(c), Food Safety Team Leader/SQF Practitioner, and (b)(6) & (b)(7)(c), Controller. An FDA 482, Notice of Inspection was issued to Ms. Flowers. Ms. Flowers explained Mr. Keith Arnold, Kitchen Manager was the most responsible person but was not present at the time of issuance of the FDA 482 and in his absence, she is the next most responsible person. Mr. Arnold was performing a site visit at (b) (4) when the inspection was initiated per Ms. Flowers.

I informed management their firm was identified as a recipient of at least two contaminated shipments of beef tallow containing pentobarbital that was purchased from (b) (4) . Ms. Flowers explained they received notification in person from (b) (4) on Tuesday, May 8th, 2018 that three lots of beef tallow were contaminated. Ms. Flowers provided copies of shipping documents including COA, Tank Cleaning Verification, and Bills of Lading for Beef Tallow lots 20, 21, and 22 (Exhibit 1). Per Ms. Flowers (b) (4) included Lot 22 in their notification because laboratory results were still pending and it was top loaded on lot 21 when received at the firm. (b)(6) & (b) also provided a list of beef tallow shipments received at the firm from (b) (4) since January 2017-present (Exhibit 2). The firm did not receive the notification letter from Pennsylvania Department of Agriculture per Ms. Flowers (Attachment 1). I provided a copy of the letter to her for their purposes.

Ms. Flowers explained the firm's operations regarding the receipt, storage, and use of beef tallow. She explained when a tanker arrives with a shipment of beef tallow, the tallow is (b) (4) . Beef Tallow is (b) (4) . (b)(6) & (b)(7)(c) explained the firm (b) (4) . Per Ms. Flowers, the firm received its tallow solely from (b) (4) . She provided an Ingredient Specification Form-Fats and Oils for Beef Fat that outlines specifications for the beef tallow (Exhibit 3). Ms. Flowers explained the beef tallow obtained from (b) (4) is received on a COA and is supposed to be sourced from (b)(6) & (b)(7)(c) and therefore, pentobarbital was not identified as a potential hazard. Ms. Flowers admitted that while (b) (4) is fully aware of this requirement there is no written agreement. She stated this is something they have overlooked and will be a requirement for future shipments of beef tallow.

Ms. Flowers informed me they were in the process of retrieving potentially affected finished

products from distributors and had quarantined the contaminated beef tallow in response to the notification received from (b) (4) . Ms. Flowers explained that (b) (4) pounds of Orijen and Acana brand dog and cat food was manufactured using the contaminated beef tallow and (b) (4) pounds of dog food had been released, sold, and shipped to third-party distributors. No potentially affected cat food was distributed per Ms. Flowers. A list of third party distributors who received the affected dog food was provided by Ms. Flowers (Exhibit 4). Additionally, Ms. Flowers explained they have ceased manufacturing products requiring beef tallow until the beef tallow on hand can be removed, a new source can be identified, and additional preventative measures are in place to prevent a reoccurrence. The firm quarantined (b) (4) pounds of contaminated beef tallow that was on hand at the time of notification.

A conference call was held with corporate management including: Jon Hickerson, Sr. VP of Operations, Jim Wagner, VP of Quality and Tricia Waddell, Internal Legal Counsel, and (b)(4) (b)(6) (b)(7)(c) , External Legal Counsel. Much of the distribution information and final decisions relating to Corrective Action Preventative Action (CAPA), and response to FDA inspection was obtained from corporate level. I asked corporate management if a Reportable Food Registry (RFR) had been filed and in response (b)(4) (b)(6) (b)(7)(c) explained that one had not been filed because the firm didn't feel the reported levels of pentobarbital was high enough to cause a health risk and based on previous FDA cases and reports. I encouraged the firm to file an RFR and explained that it is better to file the incident than not where the latter could cause administrative action if later determined the RFR was required.

On 5/17/2018, the firm transferred the contaminated beef tallow to a third-party tractor trailer tanker and intermediate bulk containers (totes) for holding until further disposition. The firm plans to hold the beef tallow until insurance claims can be made and a decision on how to properly dispose that will meet all applicable laws and regulations can be determined. The firm is considering landfill, land application as a soil amendment, and returning to (b) (4) as potential options for disposal of the contaminated beef tallow. A decision was not made regarding disposal at the close-out of the current inspection.

On 5/21/2018, I received an email from Mr. Wagner asking if we could have an update call. Caitlin and I spoke with Mr. Wagner and Mr. Hickerson. Mr. Wagner informed us Quality Assurance at the firm pulled (b) (4) finished product retain samples and sent them to (b) (4) for laboratory analysis. Mr. Wager explained retain samples were pulled from the beginning, middle, and end of the production period representing finished product made with the adulterated tallow ingredient received from (b) (4) . Mr. Wagner reported that all finished product retain samples sent to (b) (4) Laboratory were negative for pentobarbital. Exhibit 5 is a copy of the laboratory results forwarded to me via email by Mr. Wagner. The laboratory analysis report was prepared for (b)(4) (b)(6) (b)(7)(c) . (b)(4) (b)(6) (b)(7)(c) was the identified submitter of the retain samples to (b) (4) Laboratory on behalf of the firm.

Additionally, Mr. Wagner reported they are no longer doing business with (b) (4) . Mr. Hickerson pointed out they have not resumed manufacturing of product containing beef tallow. Mr. Hickerson also asked if FDA CVM would have any issue with the firm sending the adulterated

tallow back to (b) (4) for their handling/disposal. I explained to Mr. Hickerson if they dispose of via landfill or redistribute as a soil amendment, it is their responsibility to ensure all laws and regulations are met. Mr. Hickerson indicated that he understood and asked if they sent it back to (b) (4) they wanted FDA's input and knowledge of it so it wouldn't end up back in the food chain.

On 5/23/2018, a close-out meeting was held with firm management. Those present during close-out discussions included: Ms. Flowers, (b)(6) & (b)(7)(c), (b)(6) & (b)(7)(c), and Mr. Arnold. Mr. Wagner and Mr. Hickerson were also present via conference call.

During general discussions with firm management, Mr. Arnold and Ms. Flowers informed us they are pursuing (b) (4) for beef tallow. Ms. Flowers explained testing for pentobarbital will be required on all future shipments of tallow and reported on a certificate of analysis prior to acceptance and subsequent use at the firm.

Mr. Wagner reported (b) (4) pounds of affected dog food was further distributed to the store/consumer level. The firm does not plan (b) (4) . Mr. Wagner explained their decision to (b) (4) . He explained given the (b) (4) The firm still plans to (b) (4) finished products made using the contaminated beef tallow. Mr. Wagner explained they plan to (b) (4) all the retrieved dog food and quarantined cat food made with the contaminated beef tallow.

I followed up with firm management in regards to their question about sending the contaminated beef tallow back to (b) (4) I explained to firm management FDA would not object to sending back the contaminated beef tallow if it was relabeled and identified as unfit for human and/or animal consumption. Otherwise, it may be considered as shipping an adulterated product in interstate commerce. Mr. Hickerson acknowledged the concern and assured us if they chose to send the adulterated beef tallow back to (b) (4) , they would relabel it unfit for food use and document the chain-of-custody back to (b) (4) . Mr. Hickerson indicated their intention to keep FDA informed regarding the disposition of the beef tallow, destruction of affected finished products, and any new developments they may encounter. I provided them with the district compliance officers contact information assigned to this case for future correspondence.

The FSMA final rules for Sanitary Transportation of Human and Animal Food Fact Sheet, and Preventive Controls for Animal Food, as well as, the Reportable Food Registry (RFR) and Food Facility Registration Biennial Registration Renewal handouts were provided to firm management. Firm management was advised of consequences available to FDA for failure to comply with the FD&C Act and applicable regulations.

EXHIBITS COLLECTED

EX 1 Shipping documents for beef tallow lots 20, 21, and 22 containing pentobarbital received from (b) (4) (11 pages)

EX 2 List of beef tallow shipments received at the firm from (b) (4) since January 2017-present (1 page)

EX 3 Ingredient Specification Form-Fats and Oils (2 pages)

EX 4 List of third party distributors whom received the affected dog food (2 pages)

EX 5 Laboratory analysis report for finished product retain samples made with adulterated beef tallow contaminated with pentobarbital (2 pages)

ATTACHMENTS

FDA 482, Notice of Inspection (3 pgs.)

ATT 1 Notification letter from Pennsylvania Department of Agriculture identifying pentobarbital in shipments of beef tallow sent by (b) (4) to the firm (6 pages)

Justin N. Henson, Investigator

Caitlin L. Almonrode, Investigator