

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd, Suite 1500 Chicago, IL 60661 (312) 353-5863	DATE(S) OF INSPECTION 01/10-11/2017, 02/01-02/2017, 02/08/2017
	FEI NUMBER 1480280

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joel A. Sher, President

FIRM NAME Evanger's Dog and Cat Food Company, Inc.	STREET ADDRESS 221 South Wheeling Road
CITY, STATE AND ZIP CODE Wheeling, Illinois 60090	TYPE OF ESTABLISHMENT INSPECTED Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.


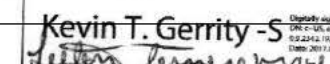
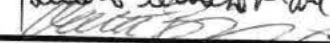
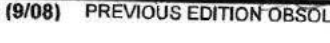
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

The following observations were found to be adulterated under the Federal Food, Drug, and Cosmetic Act:

A food shall be deemed to be adulterated if it bears or contains any added poisonous or added deleterious substance that is unsafe within the meaning of section 402. Specifically,

- 1.) Your low-acid canned dog food product labeled in part "EVANGER'S***HAND PACKED HUNK OF BEEF AUS JUS***NET WT 12 OZ***" and coded "1816E06HB13" was found by chemical analysis to contain the barbiturate drug pentobarbital.
- 2.) Your low-acid canned dog food product labeled in part "AGAINST the Grain***GRAIN FREE PULLED BEEF with Gravy***DINNER FOR DOGS***NET WT 12 OZ***" and coded "2415E01ATB12 BEST DEC 2019" was found by chemical analysis to contain the barbiturate drug pentobarbital.
- 3.) On 01/10/2017 and 01/11/2017 condensate dripped throughout your processing facility from the building framing, ceiling, walls, and from tarps suspended above food processing areas, including condensate dripping directly into open cans of the in-process low-acid canned dog food product HUNK OF BEEF, and also into multiple open totes of raw meats including beef intended for your canned dog food product HUNK OF BEEF.
- 4.) The floors throughout your processing facility are pitted, cracked, and otherwise damaged causing pooled water in areas where food is exposed including where open cans of in-process HUNK OF BEEF dog food are staged on a wooden pallet immediately upon the damaged floor.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kevin Gerrity, Investigator	DATE ISSUED 02/14/2017
	EMPLOYEE(S) SIGNATURE   	EMPLOYEE(S) NAME AND TITLE (Print or Type) Dariusz Galezowski, Investigator Lee Terry Moore, Investigator Mathew Buenconsejo, Investigator	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd, Suite 1500 Chicago, IL 60661 (312) 353-5863	DATE(S) OF INSPECTION 01/10-11/2017, 02/01-02/2017, 02/08/2017
	FEI NUMBER 1480280

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joel A. Sher, President

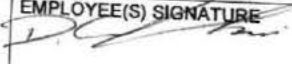
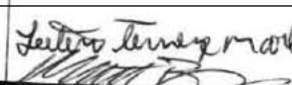
FIRM NAME Evanger's Dog and Cat Food Company, Inc.	STREET ADDRESS 221 South Wheeling Road
CITY, STATE AND ZIP CODE Wheeling, Illinois 60090	TYPE OF ESTABLISHMENT INSPECTED Manufacturer

5.) Additional sanitary conditions observed on 01/10/2017 and 01/11/2017 include peeling paint and mold on walls throughout the processing facility including in areas where food is exposed, a live fly-like insect in the HUNK OF BEEF hand-packing area during processing, and an open sanitary sewer within approximately 25 feet of two food storage trailers and one food processing trailer at the rear exterior of the facility.

6.) You lack operating refrigerated storage facilities or other means of controlling the temperature exposure of raw meats during thawing, storage, and processing.

On 01/10/2017 and 01/11/2017 multiple approximate (b) (4) of raw beef and other raw meats in various stages of thawing were stored at ambient temperature inside your processing facility and also at ambient temperature inside three trailers on the exterior grounds of your facility. The exterior ambient temperatures were below freezing on these two inspection days. There was frozen ice containing a blood-like substance across the floors of the three trailers, and also on the ground immediately outside of two of the trailer doors.

On 01/11/2017 hand packing operations started at approximately (b) (4) for your HUNK OF BEEF canned dog food. Open cans of beef were staged on a pallet at ambient temperature during the hand packing process. At the conclusion of the inspection at approximately 2:00 PM the hand packing operation was still in process, with the first open cans of beef that were packed at approximately (b) (4) still staged at ambient temperature on the bottom layer of the pallet of hand-packed cans.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kevin Gerrity, Investigator Dariusz Galezowski, Investigator Lee Terry Moore, Investigator Mathew Buenconsejo, Investigator	DATE ISSUED 02/14/2017
	EMPLOYEE(S) SIGNATURE 		

Add Continuation Page