

**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 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/10-12/2017, 01/31/2017
	FEI NUMBER 3010876031

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Joel A. Sher, Manager

FIRM NAME Nutripack LLC	STREET ADDRESS 2210 W 162nd St
CITY, STATE AND ZIP CODE Markham, Illinois 60428	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,

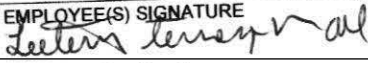


- 1.) Your low-acid canned dog food product labeled in part "AGAINST the Grain***GRAIN FREE PULLED BEEF with Gravy***DINNER FOR DOGS***NET WT 12 OZ***" and coded "2415E01ATB12 BEST DEC 2019" was found by chemical analysis to contain the barbiturate drug pentobarbitol.

A food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Specifically,

- 2.) On 01/10/2017, 01/11/2017, 01/12/2017 and 01/31/2017 condensate dripped throughout your processing and storage facility from the building frame and ceiling.

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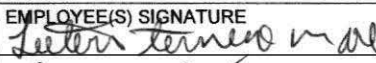
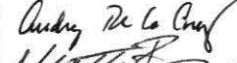

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) LeeTerry Moore, Investigator	DATE ISSUED 02/14/2017
		Audrey De La Cruz, Investigator	
		Matthew Buenconsejo, Investigator	

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- Condensate dripping directly above open cans of the in-process low-acid canned dog food product COOKED CHICKEN LOAF and HAND PACKED CHICKEN.
 - Excessive pooling of condensation on pallets of stored product.
 - Excessive pooling of condensation on the floor of the shipping and receiving area.
- 3.) Frozen raw meats for processing are prepared while having direct contact with the insanitary, bare, paint peeling and unprotected concrete floor of the processing facility.
- 4.) On 01/31/2017 employees were observed cutting raw chicken parts on untreated wooden building construction lumber.
- 5.) Your storage facility was observed to have avian activity. Specifically, on dates 01/10/2017, 01/11/2017, 01/12/2017 and 01/31/2017;
- Birds were observed feeding on spilled pet food found in the expansion joints of the concrete floor.
 - Resting in rafters.
 - Flying through the warehouse.
- 6.) 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 COOKED CHICKEN LOAF and HAND PACKED CHICKEN dog food are staged on a wooden pallet immediately upon the damaged floor.

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