DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969	7/7/2021-7/15/2021* FEI NUMBER 3000243857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Akiva Boclin, President

FIRM NAME	STREET ADDRESS
The Lennox International, Inc	930 New Durham Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Edison, NJ 08817-2214	Manufacturer and Importer

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 OBSERVED:

OBSERVATION 1

You did not evaluate each known or reasonably foreseeable hazard for each type of animal food you manufacture, process, pack or hold in your facility.

Specifically,

Your firm's hazard analysis did not include an evaluation of the known or reasonably foreseeable hazards for your rawhide dog treats. Your firm's hazard analysis does not include an evaluation of the known or reasonably foreseeable hazards for that may be introduced by your repacking operations, or by your manufacturing process of (b)(4) and drying of rawhide dog treats.

OBSERVATION 2

You did not verify that your preventive control(s) are consistently implemented and effective through environmental monitoring.

Specifically,

Your hazard analysis for animal part products has identified recontamination with environmental pathogens during the repacking process of your ready-to-eat bully sticks as a hazard requiring a sanitation control. You have not implemented an environmental monitoring program in the (b)(4) (b)(4) room where the repacking of ready-to-eat bully sticks operations take place. Furthermore, your written procedure does not document the entire cleaning and sanitizing process explained by your

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kyle D Covill, Investigator	X Kyle D Covill Investigator Signed By: 2001656079 Date Signed: 07-15-2021 11:31:17	7/15/2021

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firm's management. Your written procedures do not include mandatory elements of an environmental monitoring program such as, but not limited to: the test microorganism, locations for sampling, frequency of sampling, number of samples to be collected, timing and frequency for collecting and testing environmental samples, the test conducted, the laboratory conducting the testing, and the corrective actions that will occur if a pathogen is isolated.

OBSERVATION 3

Your sanitation controls did not include procedures, practices, and/or processes that ensure sanitary conditions are adequate to significantly minimize or prevent hazards.

Specifically,

Your firm's hazard analysis for animal part products has identified recontamination with environmental pathogens during repacking of ready-to-eat bully sticks as a hazard requiring a sanitation control which takes place in the (b)(4) room. You have identified the written procedure for employee hand-washing labeled Wash Your Hands Well as the written procedure for verification activity of the sanitation control. Your procedure documents employees should wash their hands with soap for (b)(4) , then apply hand sanitizer. Your procedure states employees should wash their hands before starting work, when changing products, and when returning after lunch and bathrooms. On 07/07/2021, I observed seven (7) employees exiting the firm's break room, use hand sanitizer, then don gloves and return to (b)(4) to began repacking ready-to-eat natural rawhide pet treat without washing their hands. You explained this procedure is applicable to all employees, including the employees responsible for packing ready-to-eat bully sticks in the (b)(4) room. Furthermore, you have not identified or implemented a monitoring activity for hand-washing related to your firm's sanitation control.

OBSERVATION 4

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Your records are not actual values and observations obtained during monitoring and verification activities.

Specifically,

Your firm's hazard analysis for animal part products has identified recontamination with environmental pathogens during repacking of ready-to-eat bully sticks as a hazard requiring a sanitation control which takes place in the (b)(4) room. You have identified a written procedure named Stainless Steel (b)(4) Cleaning Procedures as the written procedure for preparing the (b)(4) your firm is using as a sanitizer, as well as the use of (b)(4) (b)(4)) swab as an indicator of the thoroughness of immediate cleaning and sanitization of the (b)(4) room, (b)(4) You have also identified the monitoring record labeled Cleaning Swapping (b)(4) as the record for monitoring the (b)(4) (b)(4) (b)(4) and results of the (b)(4) swab. This record also serves as the monitoring record for the implementation of the sanitation control. The written procedures do not instruct employees to write the actual values of the (b)(4) (b)(4) the value displayed on the (b)(4) reader, or the number of (b)(4) swabs analyzed. The monitoring record does not reflect the actual (b)(4) (b)(4) . The monitoring record does not reflect the actual value displayed as relative light units for the results of the (b)(4) swab.

Furthermore, your sanitation control monitoring record labeled Cleaning Swapping (b)(4) are not reviewed by a preventive controls qualified individual within seven (7) days of the creation of the document.

OBSERVATION 5

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You did not establish written procedures for monitoring, including adequate frequency for your preventive controls.

Specifically,

Your firm's hazard analysis for animal part products has identified a biological hazard of *Salmonella spp.* as a hazard which requires a preventive control. You have identified sterilization (b)(4) as the process to control *Salmonella spp.* You have identified Controls and Inspections Guidelines on Containers when Arriving from Foreign Suppliers as the written receiving procedure and monitoring record for sterilization (b)(4). The written procedure does not include a review of the sterilization report as appropriate prior to or at receiving of the products that have been (b)(4) as the process control within the United States.

Furthermore, your monitoring records of sterilization (b)(4) are not reviewed by a preventive controls qualified individual within seven (7) days of the creation of the document.

OBSERVATION 6

You did not determine which verification activity or activities were needed to provide adequate assurances that a food you obtain from a foreign supplier is produced in compliance with processes and procedures that provide the required level of public health protection.

Specifically,

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Your Foreign Supplier Verification Program's (FSVP) hazard analysis of pig ear pet treats identified a biological hazard of *Salmonella spp.* Your FSVP verification activity does not include an annual onsite audit of foreign suppliers for a known or reasonably foreseeable hazard that may result in a serious adverse health consequence or death to humans or animals.

OBSERVATION 7

Your product testing procedures are not complete.

Specifically,

Your firm's hazard analysis for animal part products has identified a biological hazard of *Salmonella spp.* as a hazard which requires a preventive control. You have identified sterilization (b)(4) as the process control for *Salmonella spp.* You have identified finished product testing as a verification activity completed after sterilization (b)(4). Your written procedure labeled Sampling for Testing Procedures does not include mandatory elements such as but not limited to: identifying the test microorganism, frequency of testing, number of samples to be collected, laboratory conducting the testing, the test being conducted including the analytical method, and corrective action procedures.

***DATES OF INSPECTION**

7/07/2021(Wed), 7/08/2021(Thu), 7/09/2021(Fri), 7/12/2021(Mon), 7/15/2021(Thu)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) 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. A copy of such report shall be sent promptly to the Secretary."