

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 2/4/2019-2/8/2019*	
		FEI NUMBER 3000204829	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jeff Liao, Owner			
FIRM NAME Topway Enterprises, Inc		STREET ADDRESS 4001 Briarpark Dr	
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77042-5319		TYPE ESTABLISHMENT INSPECTED Manufacturer	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1</p> <p>You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice, condition and cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, maintenance of hand washing, hand sanitizing, and toilet facilities and protection of food, food packaging material, and food contact surfaces from adulteration.</p> <p>Specifically, on 2/4/2019, your production room employees were not monitoring the sanitation conditions and frequency to assure conformance with the Good manufacturing practices as evidence by the following observations:</p> <ul style="list-style-type: none"> • The stainless-steel table located along the north wall of the processing room that is used for wrapping processed fish fillets and loins was found to be unclean. There was residue from the previous days operation on the table while an employee was observed wrapping raw fish. • The (b) (4) individual fish cutting tables located on the east wall of the production room were found to be unclean and had residue from the previous days operations. The cutting tables were being used to process fresh tuna and salmon during the inspection. The plastic cutting surfaces were found to be scored and chipped by the knives and other utensils that are used by the production room employees to process the raw fish. The damaged areas were found to be holding residue from previous fish processing 			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Charles B Steinmiller, Investigator Lakesha D Debardelaben, Investigator Christopher J Hurst, Investigator		DATE ISSUED 2/8/2019
			Christopher J Hurst Investigator Signed By: Christopher J Hurst-S Date Signed: 02-08-2019 12:19:41 X

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<p>operations.</p> <ul style="list-style-type: none"> • The stainless-steel table located along the west wall of the production room that is used to hold the final containers used to package the processed raw tuna and salmon for shipment to the firm's customer was found to be unclean. Residue from previous production operations was found on the corner of the table. • The knives and other utensils including fish scalers, a hand saw, an ice shovel and metal pot scrubber used in the production of fresh raw salmon and tuna for raw consumption were found to be unclean. There was fish residue and white Styrofoam from shipping containers found on the utensils. • The white plastic insulated cooler used to hold fresh fish during process was found to be in poor condition and was not clean. There were cracks in the outer surface of the cooler which allowed for the insulation to be exposed. The cooler also had a brown residue on the inner surface walls. • The metal walls of the production room were found to be unclean. There were remnants of previously process fish and other production residue on the surface of the walls adjacent to the fish cutting tables. • There was residue found on the exterior of the ice machine and on the outer door of the ice machine which contains the ice. The ice is used to maintain the temperature of the fresh fish that is processed for raw consumption by the consumer. • The paper towel dispensers in the production room were found to be unclean. There was residue from previous production operations on the exterior of the paper towel holders. There was a black mold like substance observed on the opening where the paper towels are dispensed. • The firm's (b) (4) residual for the sanitizer solution is not being routinely measured during cleaning operations. The work surfaces are sanitized with a solution of (b) (4) • The three-compartment sink was not set up appropriately to wash, rinse and sanitize the firm's processing utensils. There was no soap or sanitizer solution in the sink during the fresh fish processing operations. 			
<p>OBSERVATION 2</p> <p>Your sanitation control records do not accurately document the conditions or practices observed at your firm.</p> <p>Specifically, your firm's sanitation records "SSOP PLAN" dated 2/2/2019 and 2/4/2019 do not reflect the actual sanitary conditions in the production room as well as the adjacent fresh fish storage cooler. The sanitation record</p>			
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<p>dated 2/2/2019 identifies that the Post Op sanitary conditions are satisfactory. On the morning of 2/4/2019, at approximately 10 a.m., your firm resumed manufacturing operations to produce fresh tuna and fresh salmon which is intended to be consumed raw by the end user. The following conditions were noted by the inspection team upon entering the fresh raw fish production area of your facility:</p> <ul style="list-style-type: none"> • The stainless-steel table located along the north wall of the processing room that is used for wrapping processed fish fillets and loins was found to be unclean. There was residue from the previous days operation on the table while an employee was observed wrapping raw fish. • The (b) (4) individual fish cutting tables located on the east wall of the production room were found to be unclean and had residue from the previous days operations. The cutting tables were being used to process fresh tuna and salmon during the inspection. The plastic cutting surfaces were found to be scored and chipped by the knives and other utensils that are used by the production room employees to process the raw fish. The damaged areas were found to be holding residue from previous fish processing operations. • The stainless-steel table located along the west wall of the production room that is used to hold the final containers used to package the processed raw tuna and salmon for shipment to the firm's customer was found to be unclean. Residue from previous production operations was found on the corner of the table. • The knives and other utensils including fish scalers, a hand saw, an ice shovel and metal pot scrubber used in the production of fresh raw salmon and tuna for raw consumption were found to be unclean. There was fish residue and white Styrofoam from shipping containers found on the utensils. • The white plastic insulated cooler used to hold fresh fish during process was found to be in poor condition and was not clean. There were cracks in the outer surface of the cooler which allowed for the insulation to be exposed. The cooler also had a brown residue on the inner surface walls. • The metal walls of the production room were found to be unclean. There were remnants of previously process fish and other production residue on the surface of the walls adjacent to the fish cutting tables. • There was residue found on the exterior of the ice machine and on the outer door of the ice machine which contains the ice. The ice is used to maintain the temperature of the fresh fish that is processed for raw consumption by the consumer. • The paper towel dispensers in the production room were found to be unclean. There was residue from previous production operations on the exterior of the paper towel holders. There was a black mold like 			
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<p>substance observed on the opening where the paper towels are dispensed.</p> <ul style="list-style-type: none"> The firm's (b) (4) residual for the sanitizer solution is not being routinely measured during cleaning operations. The work surfaces are sanitized with a solution of (b) (4) The three-compartment sink was not set up appropriately to wash, rinse and sanitize the firm's processing utensils. There was no soap or sanitizer solution in the sink during the fresh fish processing operations. 			
OBSERVATION 3			
The plant is not constructed in such a manner as to allow floors to be adequately cleaned and kept clean and kept in good repair.			
<ul style="list-style-type: none"> Specifically, on 2/4/2019 the inspection team observed the floor of the production room and fish cooler to be in poor condition. The floor of the production room is not constructed in a manner that makes it smooth and cleanable. There are large cracks in the floor and uneven concrete which allows for water to pool in the room. The production room employees were observed by the inspection team processing fresh tuna and salmon for raw consumption in the processing room. Standing water was observed in the middle of the fresh fish cooler. The floor of the cooler is cracked and damaged. A pool of black water was observed in the middle of the fish cooler room. The fresh fish cooler floor has not been washed recently as indicated by the black residue on the surface of the floor. Fresh tuna and salmon was observed being stored in the cooler at the time of the inspection. 			
*DATES OF INSPECTION			
2/04/2019(Mon), 2/05/2019(Tue), 2/08/2019(Fri)			
X Lakesha D Debardeleben Investigator Signed By: Lakesha Debardeleben -S Date Signed: 02-08-2019 12:20:32		X Charles B Steinmiller Investigator Signed By: Charles B. Steinmiller -S Date Signed: 02-08-2019 12:21:16	
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