DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	12/19/2023-2/14/2024* FEI NUMBER 3013673372

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kyle D. Lemmer, Vice President, Operations

FIRM NAME	STREET ADDRESS
Waiakea Bottling Inc	447 Kalanianaole Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hilo, HI 96720-4772	Bottle Water 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 OBSERVED:

OBSERVATION 1

You did not conduct a reanalysis of your food safety plan when required.

Specifically, you have not conducted a reanalysis of your food safety plan, 'Waiakea Bottling Inc d.b.a. Waiakea Hawaiian Volcanic Water, Food Safety Plan & System Version 2.2', last reviewed and approved on October 18, 2022, in response to consumer complaints and findings of microorganisms that are indicative of insanitary conditions or are known to be pathogenic. Your firm began receiving complaints regarding foreign objects including but not limited to apparent "mold", "white blob" and "floaters" in 1-liter bottles of your Waiakea Hawaiian Volcanic Water with lot numbers 123275 and 123276 beginning on November 16, 2023. By November 22, 2023, according to the list of complaints provided, your firm received at least 7 consumer complaints. By November 28th you received an additional 5 complaints. On November 29th someone from your management team instructed your customers to hold all products in warehouses. Your private lab testing found HPC >5700 CFU/ml, Pseudomonas Aeruginosa (b)(4), and mold at 15 CFU/ml from lot code 123275. A second analysis identified Paecilomyces lilacinus. Additionally, your QC department found elevated levels of Pseudomonas from in-house testing of lot code 123276. You eventually destroyed 2940 cases from that lot [Lot 123276].

OBSERVATION 2

Sanitizing operations were not adequate to sanitize the intended critical areas.

Specifically, your cleaning and sanitizing SOP consists of a (b)(4) schedule. You do not record the duration of (b)(4) treatments to product water contact surfaces. Further, your (b)(4)

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	Lynn L Wong, Investigator X Lynn L Wong Investigator Signed By: 1300135547 Date Signed: 02-14-2024 08:10:27	2/14/2024

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(b)(4) (b)(4) located (b)(4) is bypassed during the (b)(4) CIP (b)(4) sanitizing run. The (b)(4) (b)(4) is (b)(4)) with a (b)(4) (b)(4) and (b)(4) with (b)(4) . Additionally, the (b)(4) water CIP cycle used for all product water contact surfaces (b)(4) does not appear equivalent to those required by the regulations.

The hose (b)(4) truck to the (b)(4) tank at the facility was observed stored in a (b)(4)) outside of the facility and exposed to the environment. On 12/20/2023 the (b)(4) was observed to contain too numerous to count apparent insects and particles. In addition, your employee did not flush the hose after taking it out of the (b)(4) and prior to (b)(4) and the (b)(4) tank.

OBSERVATION 3

You did not adequately sanitize the product water-contact surfaces of all pipes and equipment used in the transportation, processing and handling of product water.

Specifically, your cleaning and sanitizing standard operating procedures (SOPs) for Clean-in-Place (CIP) of product water contact surfaces such as piping consists of a (b)(4) schedule. The (b)(4) schedule only consists of sanitizing with (b)(4) with no recorded length of time). Your (b)(4) cleaning for CIP consists of (b)(4) of (b)(4) for (b)(4) . (b)(4) for CIP consists of (b)(4) at (b)(4) with (b)(4) .

OBSERVATION 4

Your treatment of product water was not done in a manner that was effective in accomplishing the intended purpose.

Specifically, the specification sheet for your (b)(4) (b)(4) indicates there should be a (b)(4) when operating the (b)(4) at an (b)(4) . You monitor the (b)(4)

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(b)(4) of the (b)(4)(b)(4) on the (b)(4) (b)(4)water treatment reading (b)(4) ' form. In your food safety plan, it states that you will (b)(4) Readings of the (b)(4) gauges recorded on the below dates showed no difference in the (b)(4) , indicating the system is not functioning as designed and intended.

DATE	(b)(4)	(b)(4)
(b)(4)	(b)(4)	(b)(4)
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	
	(b)(4)	

OBSERVATION 5
Your written process verification procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

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Specifically, your hazard analysis in the food safety plan for bottled water identifies the hazards of pathogenic bacteria, HPC, fungus, and viruses to be controlled at the (b)(4) step. The critical limit at the (b)(4) is that the (b)(4) which corresponds to a minimum (b)(4) (b)(4)

Your verification activities do not include a review of the continuous monitoring recordings made by that (b)(4) which are recorded (b)(4) which monitors the (b)(4) operational specifications (e.g., (b)(4)). You are only reviewing the "Production line (b)(4) check form" and the (b)(4) water treatment reading (b)(4) All continuous monitoring data prior to a system update in November 2023 was deleted from the (b)(4) system

The corrective action for your (b)(4) CCP for bottled water includes that your (b)(4) will prevent water from moving forward to the filler if out of performance specifications. Your verification procedures do not include verifying the (b)(4) is functioning (b)(4) product when the critical limits are not met. Additionally, you do not perform a test of the (b)(4) at startup. The (b)(4) is located (b)(4) the (b)(4) (b)(4) You indicated there is a (b)(4) between (b)(4) once the (b)(4) meets operational specifications (e.g., (b)(4) No resanitizing of the downstream product water contact surfaces between the (b)(4) step and the (b)(4) occurs after (b)(4) .

Your verification activities do not include a calibration of the (b)(4) and (b)(4) monitors.

OBSERVATION 6

Your hazard analysis did not identify a hazard that required a preventive control.

Specifically, your hazard analysis for your bottled water only identifies the (b)(4) water treatment step as a process control for biological hazards in the water. Although your facility uses a (b)(4) to treat the

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process water as the final step prior to filling, you do not identify the (b)(4) as part of the process control. There is no other process control to eliminate the possibility of other contaminates such as the white floating matter and other foreign materials that appeared in your bottled water products. Additionally, as described in observation #4, your monitoring data for the (b)(4) between the (b)(4) demonstrates there is (b)(4) drop, indicating the system is not functioning as designed and intended.

***DATES OF INSPECTION**

12/19/2023(Tue), 12/20/2023(Wed), 12/21/2023(Thu), 12/22/2023(Fri), 1/03/2024(Wed), 1/04/2024(Thu), 1/05/2024(Fri), 1/11/2024(Thu), 1/12/2024(Fri), 1/22/2024(Mon), 1/23/2024(Tue), 1/24/2024(Wed), 1/25/2024(Thu), 1/26/2024(Fri), 2/13/2024(Tue), 2/14/2024(Wed)

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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."