Waiakea, Inc

Response to FDA Form 483 Observations

March 28, 2024

CONFIDENTIAL

WITHOUT ADMITTING ANY VIOLATION OF FEDERAL OR STATE LAW, AND WHILE RESERVING EVERY OBJECTION, DEFENSE AND RIGHT OTHERWISE AVAILABLE UNDER THE LAW, WAIAKEA INC, HEREBY SUBMITS THIS RESPONSE TO FDA'S 483 OBSERVATIONS:

FDA 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. Waialrna 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 !mown to be pathogenic. Your firm began receiving complaints regarding foreign objects including but not limited to apparent "mold", "white blob" and "floaters" in I-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 >2400 MPN/l00ml, 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].

Waiakea, Inc Response to FDA Observation 1

Waiakea, Inc is implementing measures that will address FDA Observation 1. These measures are further explained in the corrective and preventive actions below:

We have implemented an (b)(4) review of the Food Safety Plan as well as revisions as needed.

We have reviewed and conducted a reanalysis of our Food Safety Plan as of March 20, 2024. In our re-analysis of the FSP, we have added testing for pathogenic microorganisms as a hazard control. We think we understand where this came from and implemented programs to mitigate it and implement a (b)(4) to test specifically for Paecilomyces lilacinus.

The updated Food Safety Plan is available for review upon request.

WITHOUT ADMITTING ANY VIOLATION OF FEDERAL OR STATE LAW, AND WHILE RESERVING EVERY OBJECTION, DEFENSE AND RIGHT OTHERWISE AVAILABLE UNDER THE LAW, WAIAKEA INC, HEREBY SUBMITS THIS RESPONSE TO FDA'S 483 OBSERVATIONS:

FDA 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) filter located (b)(4) is bypassed during the (b)(4) CIP (b)(4) sanitizing run. The (b)(4) filter is (b)(4)) with a (b)(4) CIP (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 used to attach the (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 connecting it to the tanker and the (b)(4) tank.

Waiakea, Inc Response to FDA Observation 2

Waiakea, Inc is implementing measures that will address FDA Observation 2. These measures are further explained in the corrective and preventive actions below:

PART A

We have validated a contact time value of (b)(4) (b)(4).
Our use of (b)(4) as a sanitizing procedure is done (b)(4) and measured using (b)(4) and then recorded in a data sheet/checklist for our records showing that our CIP is in fact sanitizing our contact surfaces.

Our system does not lend itself to real-time digital data logging, but with a checklist we can verify the contact time and track data.

PART B

The (b)(4) has a corrosive effect on the membranes (ruins the integrity of the filter) instead we have opted to use a HOT CIP and Peracetic acid which more than compensates for what (b)(4) does.
Our current (b)(4) CIP is reaching temperatures of (b)(4) degrees Fahrenheit depending on the ability of our hot water heater to sustain that temperature for the CIP – We are beta testing ways of

insulating (b)(4) tank (where we've determined the loss of temperature to occur) to mitigate heat loss.

We will be adding a (b)(4) to verify the temperature of the water we're using and record that in a data sheet/checklist for our records.

PART C

In our research we've determined that NY state requires 600ppm, this should improve the efficacy of the sanitation. We have increased to (b)(4) for all hoses and fittings as well as building a trough like storage to keep them off of the ground.

WITHOUT ADMITTING ANY VIOLATION OF FEDERAL OR STATE LAW, AND WHILE RESERVING EVERY OBJECTION, DEFENSE AND RIGHT OTHERWISE AVAILABLE UNDER THE LAW, WAIAKEA INC, HEREBY SUBMITS THIS RESPONSE TO FDA'S 483 OBSERVATIONS:

FDA 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 (b)(4) 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) . (b)(4) for CIP consists of (b)(4) at (b)(4) with no recorded length of time.

Waiakea, Inc Response to FDA Observation 3

Waiakea, Inc is implementing measures that will address FDA Observation 3. These measures are further explained in the corrective and preventive actions below:

Corrective Action:

Covered in our response in Observation 1 and 2

WITHOUT ADMITTING ANY VIOLATION OF FEDERAL OR STATE LAW, AND WHILE RESERVING EVERY OBJECTION, DEFENSE AND RIGHT OTHERWISE AVAILABLE UNDER THE LAW, WAIAKEA INC, HEREBY SUBMITS THIS RESPONSE TO FDA'S 483 OBSERVATIONS:

FDA 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) filter indicates there should be a (b)(4) when operating the filter at an (b)(4) flow rate. You monitor the (b)(4) (b)(4) of the filter (b)(4) on the eWorks (b)(4) water treatment reading Temperature (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) from (b)(4) , indicating the system is not functioning as designed and intended.

Waiakea, Inc Response to FDA Observation 4

Waiakea, Inc is implementing measures that will address FDA Observation 4. These measures are further explained in the corrective and preventive actions below:

Corrective Action:

In our analysis with the supplier of the filter, we discovered that at the time the FDA representative tested the pressure, our (b)(4) In the correct mode, there would not be a pressure variation. This has been tested and confirmed.

WITHOUT ADMITTING ANY VIOLATION OF FEDERAL OR STATE LAW, AND WHILE RESERVING EVERY OBJECTION, DEFENSE AND RIGHT OTHERWISE AVAILABLE UNDER THE LAW, WAIAKEA INC, HEREBY SUBMITS THIS RESPONSE TO FDA'S 483 OBSERVATIONS:

FDA Observation 5

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

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) treatment step. The critical limit at the (b)(4) CCP is that the (b)(4) which corresponds to a minimum (b)(4) flow rate.

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 Temperature (b)(4). All continuous monitoring data prior to a system update in November 2023 was deleted from the (b)(4)

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 and diverts product when the critical limits are not met. Additionally, you do not perform a test of the (b)(4) at startup. The dive1i valve is located in the filler room after the (b)(4) filter. You indicated there is a three-minute delay between dive1i and resuming forward flow once the (b)(4) meets operational specifications (e.g., (b)(4)). No re-sanitizing of the downstream product water contact surfaces between the (b)(4) step and the divert valve occurs after (b)(4)

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

Waiakea, Inc Response to FDA Observation 5

Waiakea, Inc is implementing measures that will address FDA Observation 5. These measures are further explained in the corrective and preventive actions below:

Corrective Action:

PART A

We are working to retrieve the lost data and are working with software engineers to prevent a

data loss like this in the future.

PART B

A verification process has been implemented to create a test of the (b)(4) at start up as well as (b)(4) and (b)(4) calibration of (b)(4) and (b)(4) monitors.

WITHOUT ADMITTING ANY VIOLATION OF FEDERAL OR STATE LAW, AND WHILE RESERVING EVERY OBJECTION, DEFENSE AND RIGHT OTHERWISE AVAILABLE UNDER THE LAW, WAIAKEA INC, HEREBY SUBMITS THIS RESPONSE TO FDA'S 483 OBSERVATIONS:

FDA 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) step as a process control for biological hazards in the water. Although your facility uses a (b)(4) filter to treat the process water as the final step prior to filling, you do not identify the (b)(4) filter 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) differential between the (b)(4) demonstrates there is no (b)(4) drop, indicating the system is not functioning as designed and intended.

Waiakea, Inc Response to FDA Observation 6

Waiakea, Inc is implementing measures that will address FDA Observation 6. These measures are further explained in the corrective and preventive actions below:

Corrective Action:

Covered in our response in Observation 4 and 5.

We have also added an additional process preventative control for the (b)(4) both at the source site as well as the production facility.