



WAIAKEA BOTTLING, INC  
447 KALANIANA'OLE AVE  
HILO HI, 96720  
(424)228-4234

March 14, 2024

Darla R. Bracy  
Program Division Director  
Office of Human and Animal Operations (OHAFO)  
Program Division West 5  
U.S. Food and Drug Administration  
1431 Harbor Bay Pkwy, Room 214  
Alameda, CA 94502

*Sent via email to: [orahafwest5firmresponses@fda.com](mailto:orahafwest5firmresponses@fda.com)*

**Re: Waiakea Bottling, Inc., FEI 3013673372; FDA Form 483 Initial Response**

Dear Ms. Bracy,

We are writing to update FDA as to our plan to address FDA's observations noted in the Form 483 issued on February 14, 2024. Please note that we have been actively working and have completed several actions to address FDA observations. We have not yet provided FDA with a comprehensive response as to these completed and planned actions, mainly because we have focused our efforts on the recall that was initiated. However, please note we are prioritizing our efforts to address FDA's 483 comments and remain committed to ensuring continued compliance with all regulations. We have also engaged a third-party consultant, (b)(4), a prominent bottled water manufacturing expert with over 40 years of food safety experience.

We plan to provide FDA with a comprehensive supplemental response by March 29, 2024. We look forward to continued cooperation with the agency and remain willing and available to discuss with FDA.

Sincerely,

A handwritten signature in blue ink, appearing to read "Crystal Casas", with a stylized flourish extending to the right.

Crystal Casas  
Chief of Staff/Compliance  
[ccasas@waiakea.com](mailto:ccasas@waiakea.com)  
805-827-5507