



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

One Montvale Avenue  
Stoneham, Massachusetts 02180  
Telephone: 781.596.7700  
Facsimile: 781.596.7899

March 24, 2003

**WARNING LETTER**

**NWE-11-03W**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Jeffrey C. Villano, President  
Ultimate Brands, Inc.  
159 Bridge Street  
New Haven, CT 06511

Dear Mr. Villano:

On January 21, 2003 we concluded an inspection of your seafood processing facility, located at 159 Bridge Street in New Haven, CT. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR § 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your ready-to-eat seafood salad is adulterated, in that it 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. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

- ▶ You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR § 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and that the

cause of the deviation is corrected. However, your firm did not take corrective action to control the hazard of pathogen growth and toxin formation (other than *Clostridium botulinum*) as a result of time and/or temperature abuse when your process for seafood salad deviated from your critical limit at the finished storage critical control point. Specifically, multiple temperature excursions above 40° F, as documented by the temperature recorder for your firm's cooler, were noted by our investigators.

- ▶ You must implement the monitoring procedures that you have listed in your HACCP plan to comply with 21 CFR § 123.6(b). However, your firm did not follow the procedure for monitoring the cooler temperature at the critical control point of finished product storage to control the hazard of pathogen growth and toxin formation (other than *Clostridium botulinum*) as a result of time and/or temperature abuse listed in your HACCP plan for seafood salad. Specifically, temperature recording charts were not always replaced on a weekly basis. Our investigators observed six charts for the period of time from the second week of July 2002 to the first week of October 2002 with overlapping pen tracings (indicating the use of the same chart for more than one week).
- ▶ You must maintain adequate sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR § 123.11(c). However your firm did not maintain sanitation monitoring records for any of the areas of sanitation required for the processing of ready-to-eat seafood salad on different weekly production runs between [REDACTED] and [REDACTED]. For [REDACTED] other weekly runs, records were incomplete. In addition, for [REDACTED] production runs of seafood salad, the weekly sanitizer test did not coincide with the actual day of the production run.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as a revised HACCP plan for cooked ready-to-eat seafood salad, examples of associated monitoring records, or any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

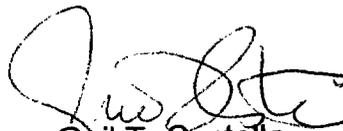
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

During this inspection our investigators also observed a number of deviations from the regulations pertaining to acidified foods (21 CFR Part 114). Safe procedures for manufacturing, processing, and packing acidified foods are essential to prevent conditions that are conducive to the growth of *Clostridium botulinum*. An anaerobic environment, low acidity (pH greater than 4.6), storage at room temperature, and high water activity are conditions that can lead to the growth of these bacteria and the subsequent production of a potent and potentially lethal toxin. The following deviations were noted:

- 1) Scheduled processes have not been established for butternut ginger pesto and grilled pepper pesto, as required by 21 CFR § 114.83.
- 2) Information on the scheduled processes for these two products was not provided to FDA prior to packing, as required by 21 CFR § 108.25(c)(2).
- 3) Processing and production records are not always properly maintained to show adherence to a scheduled process, as required by 21 CFR § 114.100(b).
- 4) Your firm does not have a plan for recalling products that may be injurious to health, as required by 21 CFR § 108.25(e).
- 5) Products are not marked with an identifying code specifying the product contained therein, as required by 21 CFR § 114.80(b).
- 6) Operators of processing and packing systems are not under the operating supervision of a person who has attended and satisfactorily completed a school (Better Process Control School) approved by the Commissioner, as required by 21 CFR § 114.10.

When you respond within fifteen (15) working days, as requested above, you should also let us know what actions you have taken or will take to correct the deviations related to your firm's acidified food manufacturing practices. Please send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.596.7751**.

Sincerely,



Gail T. Costello  
Director  
New England District

cc:

