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One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER

NWE-35-00W

VIA FEDERAL EXPRESS

July 25, 2000

Mr. Nick Nickerson, President
Cape Quality Bluefin, Inc.
249 Great Western Road
South Dennis, MA 02660

Dear Mr. Nickerson:

We inspected your firm, located at 249 Great Western Road, South Dennis, MA 02660 on June 8 and 9, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh tuna to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a HACCP plan that lists the critical limits that must be met, to comply with CFR 123.6(c)(3). However, your firm's HACCP for tuna does not list a critical limit at receiving critical control point to control histamine.

Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective plan for tuna at receiving, processing, and brining to control histamine is not appropriate. For example, when product is processed not consistent with your plan you may choose to reject the product or analyze the product for histamines. You may refer to the Hazards Guide for more information.

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

Please respond in writing within fifteen working days from the receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of forms and monitoring records of 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.

We also have received your letter of June 20, 2000 and have reviewed this submission before sending this letter.

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 (21CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You may direct your reply to Richard B. Midwood, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Midwood at (781) 279-1675 extension 1730.

Sincerely,



Gail T. Costello
District Director
New England District Office

cc: Mr. Greg LaFranchise, Technician
Cape Quality Bluefin, Inc.
249 Great Western Road
South Dennis, MA 02660