



Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

**WARNING LETTER**

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

Zohar Norman, President  
Blue & White Food Products Corp.  
24-20 49<sup>th</sup> Street  
Astoria, NY 11103

March 9, 2000

Ref: NYK-2000-43

Dear Mr. Norman:

We inspected your firm located at the above address on February 11-16, 2000 and found that you have serious deviations from the Seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). These deviations, some of which were previously brought to your attention in our letter of May 19, 1999, cause your ready-to-eat seafood salad and spread products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm did not have a HACCP plan for smoked whitefish salad and lox (smoked nova) spread to control the food safety hazards of *Clostridium botulinum* toxin formation and pathogen growth and toxin formation as a result of time/temperature abuse. Further, your firm did not have a HACCP plan for tuna salad to control the food safety hazard of scombrototoxin (histamine) formation.
2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for the sanitation items identified in 21 CFR 123.11(b), such as: safety of the water; cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand washing and toilet facilities; storage and handling of toxic compounds; protection from adulterants; employee health; and exclusion of pests.
3. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR

123.12(a)(2)(i). However, your firm did not have a product specification for smoked mackerel imported from Israel.

4. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the Seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for smoked mackerel manufactured by ██████████ in Israel.

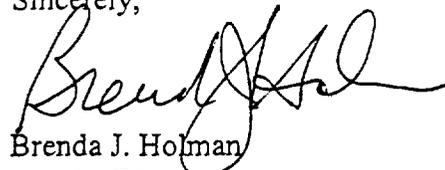
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond within three weeks from your 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 or 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 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have any questions regarding any issue in this letter, please contact Mr. Goldwitz at 718/340-7000 ext. 5582.

Sincerely,



Brenda J. Holman  
District Director