



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

m4982n

Telephone (973) 526-6008

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

**Certified Mail  
Return Receipt Requested**

File # 01-NWJ-11

December 16, 2000

Mr. Frank C. Pollera  
President  
Missa Bay, Inc.  
508 Center Square Road  
Swedesboro, NJ 08085

Dear Mr. Pollera:

We inspected your seafood processing facility located at the above address from November 2-16, 2000, and found serious violations of the Seafood Hazard Analysis and Critical Control Point or HACCP regulations (Title 21, Code of Federal Regulations or CFR, Part 123), and the regulations covering the Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (21 CFR 110) and Food Labeling (21 CFR 101). Those violations described below cause your products referenced below to be adulterated and misbranded under the Federal Food, Drug and Cosmetic Act (the Act). The violations were:

1. You must have a HACCP plan that lists food safety hazards that are reasonably likely to occur and a plan that lists critical control points to control those identified food safety hazards to comply with 21 CFR 123.6(c)(1) and (2). Your HACCP plan for your Seafood Salad does not include the hazard of Clostridium botulinum toxin formation. Your HACCP plans for Seafood, Tuna and Shrimp Salads do not include the hazards of Staphylococcus aureus and Bacillus cereus.
2. You must have a HACCP plan that lists the critical control points for food safety hazards throughout your process to comply with 21 CFR 123.6(c)(2). Your HACCP plan for Shrimp Salad does not include thawing of frozen shrimp as a critical control point. All HACCP plans do not include time of processing or time to chill as a critical control point, either alone or in combination with temperature monitoring. Non-ferrous metals (aluminum can fragments) are not included in the HACCP plan for Tuna Salad.
3. You must implement the monitoring procedures listed in your HACCP plans to comply with 21 CFR 123.6(b). Thawing temperatures for frozen vacuum-packaged surimi were not taken

and/or recorded for the production days of October 30-31, and November 1 and 20. Those temperatures are listed as a critical control point in your HACCP plans. Inappropriate thawing methods for frozen surimi and shrimp were used throughout August – November, 2000, including outside thawing with no temperature monitoring and the use of hot water baths and sprays. Temperature and sanitizer strength monitoring were not recorded on November 2. In addition, our investigators noted instances where temperature and sanitizer strength monitoring are not recorded by your employees at the time of observation.

4. You must take appropriate corrective actions when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). Records for temperature monitoring of thawing frozen vacuum-packaged surimi on thirteen dates (August – November, 2000) indicate that product was thawed for a period of time in excess of 24 hours without opening the packages. Excessive temperatures were noted for Tuna Salad on August 8 and 29 and for “special” Tuna Salad on October 19. However, your firm took no corrective action when your process temperatures exceeded the critical limit of 45° F.
5. You must have a HACCP plan that includes critical limits at critical control points that are adequate to control food safety hazards to comply with 21 CFR 123.6(c)(3). Your HACCP plan for Seafood Salad indicates a critical limit during thawing of frozen vacuum-packaged surimi of less than 45° F. This maximum temperature of 45° F is too high to arrest C. botulinum toxin formation and proliferation.
6. You must implement the recordkeeping system in your HACCP plans to comply with 21 CFR 123.6(b). Monitoring records denoted times pre-recorded on them. Recording individuals’ signatures or initials were absent from monitoring records. Monitoring records require the name of your firm and location.
7. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). Our investigators observed sanitation deficiencies relating to the prevention of cross-contamination by employees; the maintenance of hand and utensil sanitizer stations; water safety due to inadequate or absent backflow-prevention; and the inappropriate storage of toxic chemicals, including an insecticide, in food preparation areas. The presence of live beetles and fruit flies were recorded on sanitation monitoring records for September 8 and October 27. A restroom check on October 24 showed no paper towels present. No corrective actions to these two deficiencies (if taken) were documented. In addition to sanitation monitoring, you must record that monitoring and document all corrective actions taken when adverse sanitation conditions are noted.
8. Your HACCP plans for seafood products must be developed, modified and re-assessed by an individual(s) trained in HACCP principles, either by experience or FDA-recognized formal training, to comply with 21 CFR 123.10. A person or persons of this caliber should also perform the record review.
9. Your HACCP plans for seafood products must bear mandatory information and components to comply with 21 CFR 123.6(c). Reference to monitoring records for critical control points needs to be made. Your HACCP plans must be signed and dated.

Our investigators also noted a number of insanitary conditions and unacceptable practices in your facility. They included:

- Use of an [REDACTED] solution in conjunction with a chlorine dioxide solution for pre-soaking of fresh fruits and vegetables.
- Failure to rinse fruits and vegetables with potable water following soaking in chlorine dioxide.
- The employee handsink in the raw material and fruit preparation area did not dispense hot water, had no backflow prevention device and drained via a hose to a drain located on the floor. The handwashing sink in the potato room also drained directly onto the floor.
- Water hoses in the salad and raw produce areas were observed to be stored on the floor.
- Processing employees were incorrectly using the [REDACTED] device that measures food surface temperatures. Our investigators observed employees to point the device at a salad product instead of wand or scanning the laser until a hot spot is recorded, as the [REDACTED] manufacturer directs in the product instructions.
- The absence of validation or other studies to demonstrate that the [REDACTED] temperature measuring device and the [REDACTED] computerized cooler and freezer control system are accurate for their intended use.
- Inspections of the translicer, kettle hood, onion separator, and fruit cut table showed unclean surfaces. That equipment was re-sanitized, but not re-cleaned and not re-inspected following the second sanitization.
- The men's restroom is inadequate in that there is only one toilet for approximately 35 male employees.

In addition, our investigators noted two product labeling deficiencies. The presence of monosodium glutamate in the Seafood and Tuna Salads and tricalcium phosphate in your Tuna Salad was not declared. 21 CFR 101 requires those two preservatives to be declared on the product labeling.

Finally, we are evaluating FDA-483 point 10, regarding the use of ultraviolet light on raw ingredients in the processing of your finished salads. We will contact you when that review is complete.

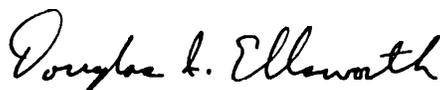
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the current good manufacturing practice for human food. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You should take prompt action to correct the violations listed above, as well as any other deviations you have knowledge of. Corrections should include the establishment or refinement of HACCP controls, procedures, monitoring, and training designed to prevent future violations. If you fail to promptly correct these violations, we may take further action to seize your products, enjoin your firm from operating, or criminally prosecute your firm and/or responsible individuals.

We also encourage you to contact Mr. Robert McCullough, Supervisory Investigator, at 856-783-1420, to inquire about HACCP training opportunities.

Please respond in writing within 15 days from receipt of this letter. Your response should outline the specific steps you are taking to correct the deviations. Please send your reply to the attention of Kirk D. Sooter, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, Third Floor, Parsippany, NJ 07054. If you have any questions regarding any issue in the letter, please contact Mr. Sooter at 973-526-6008. Also, please provide additional information regarding the use of the ultraviolet light in processing.

Sincerely yours,

A handwritten signature in black ink that reads "Douglas I. Ellsworth". The signature is written in a cursive style with a large initial 'D'.

Douglas I. Ellsworth  
District Director