



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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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 # 00-NWJ-50

August 28, 2000

Robert B. Zukerman
President
M. Zukerman and Co., Inc.
270 North Delsea Drive
Vineland, NJ 08360

Dear Mr. Zukerman:

We inspected your storage facility, located at 270 North Delsea Drive, Vineland, New Jersey from July 19-20, 2000 and found serious deviations from the Seafood Hazard Analysis and Critical Control Point or HACCP regulations (Title 21, Code of Federal Regulations, Part 123) and the regulations covering the Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (Title 21, Code of Federal Regulations, Part 110). These deviations, described below, cause your products -- shrimp salad, tuna salad, tuna penne vinaigrette salad, seafood salad, clam base, crab base, lobster base, shrimp base, smoked whitefish salad, smoked salmon, smoked sable and smoked whitefish -- to be adulterated under the Federal Food, Drug and Cosmetic Act (the Act). The violations were:

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 does not have a HACCP plan for all of the above-referenced products to control food safety hazards such as *Clostridium botulinum*, *Listeria monocytogenes*, and *Staphylococcus aureus*.
2. You must have a HACCP plan that lists procedures for monitoring storage temperatures of the above-referenced products to comply with 21 CFR 123.6(c)(4). Monitoring storage temperatures controls the hazards listed in the previous item. Your monitoring records indicate that you are not consistently recording storage temperatures.
3. You must take appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take corrective action to control the *Clostridium botulinum* hazards for smoked whitefish on May 17, 2000, when the cooler temperature reached 39° F for a five-hour duration.

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4. You must adequately monitor and document sanitation conditions and practices to comply with 21 CFR 123.11(b) & (c). The sanitation conditions in question are a) the protection of your refrigerated and frozen seafood products from adulteration by chemical, physical and/or microbiological contaminants, and b) exclusion of pests from your facility.
5. Once authored, you must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). Currently, your firm is not calibrating temperature devices on your cooler to ensure that temperatures are accurate for subsequent monitoring and recording.
6. You must have an individual (either employed by your firm or as a consultant) trained in the principles and applications of HACCP, to comply with 21 CFR 123.10. That training must be either a result of attending and completing an FDA recognized curriculum or extensive job experience. Currently, you have no HACCP trained individual employed or affiliated with your firm.

In addition, our investigator noted several insanitary conditions in your facility. They include the presence of rodent excreta pellets and live insects, broken food containers (which serve as an attractant for pests), and excessive dust and debris in the food storage area.

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 above deviations, 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.

To facilitate your understanding of HACCP, we are enclosing a copy of those regulations. We also encourage you to contact Mr. Robert McCullough, Supervisory Investigator, at 856-783-1420, to inquire about HACCP training opportunities. A Seafood HACCP Alliance course is scheduled to take place October 3-5, 2000.

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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.

Sincerely yours,

Edward H. Wilkins, for
Douglas I. Ellsworth
District Director