DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street, N.E.
Atlanta, GA 30309

Telephone: 404-253-1181
FAX: 404-253-1202

September 16, 2005

WARNING LETTER
05-ATL-26

VIA FEDERAL EXPRESS

Donald Garvey, Vice President of Distribution
Merchants Distributors, Inc.
5005 Alex Lee Blvd.
Hickory, North Carolina 28601

Dear Mr. Garvey:

We inspected your seafood/multiple food storage warehouse, located at 5005 Alex Lee Blvd., Hickory, North Carolina on August 24-25, 2005. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or 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 products (various seafood salads and spreads) are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violations were as follows:

1. You must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for your assorted seafood salads and spreads such as, tuna salads, salmon salads, & crab salads, to control the hazard of pathogens and histamine formation in scombroid toxin-forming fish.

2. You must implement the monitoring procedures and frequency that you have listed in your HACCP plan for scombroid toxin-forming species to comply with 21 CFR 123.6(b) and (c)(4). Your firm did not follow your HACCP monitoring procedures and frequency of monitoring for the presence of adequate ice or gel packs at critical control point of "Receiving" for control of the formation of histamine.

3. Your HACCP records used for documenting the critical control point of "Receiving" for pasteurized crabmeat do not contain the name of the seafood product, the signature or initials of the person performing the operation, and/or the date and time of the activity that the record reflects, in order to comply with 21 CFR 123.9(a). In addition, during July – August 2005 some of your HACCP monitoring records were reviewed and signed by an individual who has not received HACCP training. Review of monitoring records by a seafood HACCP trained individual is required to comply with 21 CFR 123.8(a)(3) and 123.10(c).

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

You should 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 violations. You should include in your response documentation such as HACCP and verification records, and any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulation (21 CFR Part 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 James MacLaughlin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issues in this letter, please contact Mr. MacLaughlin at (404)253-1220.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District