DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 93730d

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

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 4, 2002

File # 03-NWJ-02

Mr. Thomas A. Henrich
President
D. L. Mathews & Co. Inc.
100 Dartmouth Drive
Swedesboro, New Jersey 08085

Dear Mr. Henrich:

We inspected your firm, located at 100 Dartmouth Drive, Swedesboro, New Jersey on September 16, 17 & 23, 2002 and found that you have serious deviations from the U. S. Food and Drug Administration's (FDA) Title 21, Code of Federal Regulations, Part 123 - Fish and Fishery Products (Seafood HACCP regulations). In accordance with 21 CFR 123.6(g), the failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders that processor's fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) (Section 342(a)(4), Title 21, United States Code). Accordingly, the deviations noted at the inspection cause your ready-to-eat (RTE) seafood products, including salads, pasteurized crabmeat, jarred herring and vacuum-packed smoked fish to be adulterated within the meaning of section 402(a)(4) of the Federal Food Drug & Cosmetic Act (the Act), in that it was prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. Some of these deviations were also noted and brought to your attention at a previous inspection on May 29-31, 2001, and were the subject of a letter to your firm from FDA dated August 20, 2001.

You can find the Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov. The third edition of the Fish and Fisheries Products Hazards and Controls Guidance, which we also recommend that you use as a reference, can also be found on-line at http://www.cfsan.fda.gov/~comm/haccp4.html.

The deviations were as follows:

- Your firm does not have written HACCP plans for the secondary receipt and subsequent refrigerated storage of RTE vacuum-packed smoked fish products, pasteurized crabmeat, jarred herring products, RTE seafood salads and RTE smoked fish. In order to comply with 21 CFR 123.6(b), you must have written HACCP plans to control the potential food safety hazards of histamine formation, pathogen growth and Clostridium Botulinum toxin formation for these products. Receiving documents collected by our investigator during the inspection showed that you receive and store these products on a regular basis. Your lack of written HACCP plan(s) to control the potential food safety hazards inherent in these products was previously brought to your attention during our last inspection on May 29-31, 2001 and again in our letter dated August 20, 2001.

- You must have written HACCP plan(s) that identify the appropriate critical control points (CCPs) needed to control the food safety hazards inherent in the fish and fishery products you receive, store and distribute. You must then implement an effective record keeping and monitoring system of the CCPs identified in your HACCP plan(s) in order to comply with 21 CFR 123.6(c)(4). However, your current monitoring and record keeping system is inadequate, since you only monitored the temperatures of potentially hazardous fish and fishery products received from one of your vendors [redacted], despite receiving similar products from eight other disparate suppliers. Further, your temperature monitoring practices for the receipt and storage of potentially hazardous seafood products are inadequate. For example, only one item per each lot received was monitored for potential temperature abuse, which does not constitute a representative sample. Similarly, solely monitoring the ambient air temperature of the delivery vehicle at receipt does not constitute an adequate monitoring procedure. Your monitoring procedures for the storage of potentially hazardous fish and fishery products is also inadequate, as no monitoring procedure is in place which provides assurance that these products are continuously maintained at or below 40 ^{0}F.

Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure of your products and/or injunction.

Please 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 deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, copies of revised monitoring records 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 the delay and provide a deadline by which the corrections will be completed.

This letter may not list all 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 Current Good Manufacturing Practice regulations (21 CFR 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.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

Sincerely,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director
New Jersey District