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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-12

December 10, 2001

Nephi De Mercurio, President
Mr. Dee's Seafood 'N' Things, Inc.
3950 Jackson Road
Ann Arbor, MI 48103-1824

Dear Mr. De Mercurio:

On May 3 through 8, 2001 the Food and Drug Administration (FDA) conducted an inspection of your facility located at 3950 Jackson Road, Ann Arbor, MI. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) and the current Good Manufacturing Practice requirements for foods (GMP) (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator presented your firm with a form FDA-483 that provides the investigator's evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. In spite of some of the corrections you have made, we still find your firm in violation of 21 CFR parts 123 and 110, causing your products to be considered adulterated under the provisions of the Federal Food, Drug, and Cosmetic Act, section 402(a)(4) because of the following:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for clams and oysters does not list the critical control point of storage to control the food safety hazard of pathogen growth. In addition, this same HACCP plan should be amended to include mussels.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123(c)(3). However, your firm's HACCP plan for vacuum packed smoked fish lists a critical limit for internal temperature at the receiving critical control point that is not adequate to control *Clostridium botulinum*. Your firm's

HACCP plans lists 48° F as the critical limit for the internal temperature of vacuum packed smoked fish at the receiving critical control point. A temperature of 48° F is conducive to the growth of *Clostridium botulinum*. The Fish & Fishery Products Hazards & Control Guide, third edition, recommends an internal temperature no higher than 40° F for all vacuum packed fish in the chilled state to control *Clostridium botulinum*.

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the storage critical control point to control *Clostridium botulinum* listed in your HACCP plan for smoked vacuum packed fish. This was evidenced by the fact that the investigator reported that your firm could not produce records for the dry cooler and walk-in cooler for the period spanning February 8 through April 21, 2001.
4. You must take an 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 a corrective action to control *Clostridium botulinum* when your process for vacuum packed smoked fish deviated from your critical limit at the storage critical control point. The corrective action charge is evidenced by the fact that the investigator's review of the temperature records for your firm's dry cooler revealed that 48 out of 86 temperature readings were above 45° F. Your firm's HACCP plan for vacuum-packed smoked fish lists a critical limit of 38° F.
5. 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.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Mr. Nephi De Mercurio
Mr. Dee's Seafood 'N' Things, Inc.

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Your written reply should be directed to David M. Kaszubski, Director Compliance Branch, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext. 185.

Sincerely,



Joann M. Givens
District Director
Detroit District