



WARNING LETTER

04-BLT-05

November 12, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John T. Hutchinson, Owner
Nandau Seafood Company
759 Hacks Neck Road
Hacksneck, VA 23358

Dear Mr. Hutchinson:

From August 26 – 28, 2003 we inspected your seafood processing facility, located in Hacksneck, VA. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), 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 this part, renders the 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 crab meat is adulterated, in that the crab meat has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.*

The deviations, observed during the inspection and upon further examination of the documents collected during that inspection, are as follows:

- To comply with 21 CFR 123.7(d), you must fully document all actions taken to correct deviations from a critical limit established in your HACCP plan. Your firm did not maintain documentation of any corrective action or evaluation of at least sixteen deviations from the critical time limit for holding crab meat at room temperature during picking established in your HACCP plan dated 4-22-2003.
- After a deviation from a critical control point, your HACCP plan must be reviewed, reassessed and, if necessary, modified by an adequately trained or qualified individual to comply with 21 CFR 123.10(b). Moreover, the record review required by 21 CFR. 123.8 (a)(3) must be performed by a individual who has successfully completed appropriate HACCP training, or is otherwise qualified through job experience. However, your firm does not have a qualified person to review production records for the production of cooked crab meat, including Crab Cook Processing Records, Processing records for Picking Crabs, and Crabmeat Cooling Records. The individual presently responsible for reviewing these records (the plant manager) has not attended a training course in the application of HACCP principles for fish and fishery products

that is recognized as adequate by the U.S. Food and Drug Administration, nor is there evidence that he is otherwise qualified through job experience to perform these functions.

- You must verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented, to comply with 21 CFR 123.8. At a minimum, verification shall include a timely review of records that document, among other things, the monitoring of critical control points, the taking of corrective actions, and the calibration of process control instruments. These records must be reviewed by an individual who has been trained in accordance with 21 CFR 123.10, and must be signed and dated in accordance with 21 CFR § 123.9(2) & (3).. Your firm does not have a qualified person to review production records for the production of cooked crab meat, including the Crab Cook Processing Records, Processing records for Picking Crabs and Crabmeat Cooling Records. The individual who is responsible for review of these records has not attended a formal HACCP training course equal to one approved by the U.S. Food and Drug Administration nor has he demonstrated that he has experience equal to the training received at an approved course.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance to 21 CFR 110, including the exclusion of pests from the facility, as evidenced by one live and 6 dead flies that were noted on an inside window ledge in the crab meat packing room, 10 dead flies that were noted on the floor under a window in the picking room next to the packing room, and 6 live flies and over 12 dead flies that were noted in the screened in crab cooling area observed during the inspection on 8/26/03. No indication was noted on the Daily Sanitation Audit Form for August 26, 2003 of live or dead flies in the plant.
- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11. However your firm did not maintain sanitation monitoring records for the monitoring and corrections of problems involving: safety of water that comes into contact with food or food contact surfaces; prevention of cross-contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in microbiological contamination; and exclusion of pests from the facility. Specifically, the last complete sanitation record available was for 6/26/03, even though other records show that production took place on 6/30 through 7/11/03, 7/18 through 7/25/03 and during several days in August 2003. The next sanitation records noted were for 8/25/03 and 8/26/03. These records were not entirely filled out.
- Your records shall include mandatory descriptive information, such as the signature or initials of the person performing the relevant operation, to comply with 21 CFR 123.9. However, the HACCP records titled "Processing Record" for production in June, July and August of 2003 and the monthly sanitation record dated 7/21/03 did not contain the signature or initials of the person completing the records.

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.

Mr. John T. Hutchinson
November 12, 2003
Page 3 of 3

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as monitoring records, HACCP training 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 your delay and state when you will correct any remaining deviations.

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

Please send your reply to the Food and Drug Administration, Attention: Randy F. Pack, Compliance Officer, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have questions regarding any issue in this letter, please contact Mr. Pack at 410-779-5455.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lee Bowers', with a long horizontal flourish extending to the right.

Lee Bowers
Baltimore District Director