



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
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July 29, 2003

WARNING LETTER NO. 2003-NOL-22

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Tuan Q. Nguyen, Owner
Sharkco Seafood International, Inc.
707 Jump-Basin Road
Venice, Louisiana 70091

Dear Mr. Nguyen:

On June 23, 2003, we inspected your firm, located at 707 Jump-Basin Road, Venice, Louisiana. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (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 seafood products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they 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 <http://www.fda.gov>.

The deviations are as follows:

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR. 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Fresh Tuna, Mahi, Wahoo, Sword, Grouper, Snapper, and Amberjack lists a critical limit "Fish are Iced properly on board of vessels" at the "Receiving" critical control point that is not adequate to control scombrototoxin formation. Specifically, "Fish are Iced properly on board of vessels" only addresses the temperature control. Histamine formation also has a time element such that scombroid fish must be cooled within twelve hours after their death.
- You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Fresh Tuna, Mahi, Wahoo, Sword, Grouper, Snapper, and Amberjack lists a

monitoring procedure at the “Receiving” critical control point that is not adequate to control scombrototoxin formation. Specifically, upon receipt of histamine-forming fish, the monitoring procedure “need proper amount of ice” does not properly control the formation of histamine after harvest. Your firm lacks harvest vessel records or other documentation showing the condition of the fish from the time of harvest to delivery at your firm. Such records should reflect the method of capture, the time and date of landing or death, the method, start-date, and time of cooling, and the storage temperature of the fish.

- You must retain records at the processing facility for at least one year after the date they were prepared in the case of refrigerated products to comply with 21 CFR 123.9(b)(1). However, your firm’s receiving records for refrigerated products, specifically histamine forming fish, were only retained for one month. Our investigator found that on June 23, 2003, the only receiving records retained and available for review were for the month of June. Receiving records for the period before June 2003 were not available for review.

Our investigator documented that your firm also repackages the histamine-forming fish: King Mackerel and Blue Runner. Neither fish is included in your HACCP plan for the histamine forming fish: Fresh Tuna, Mahi, Wahoo, Sword, Grouper, Snapper, and Amberjack. All histamine-forming fish that your firm repackages should be included in the HACCP plan.

Additionally, in accordance with 21 CFR 123.9, all records required by the HACCP regulations shall include: the date and time of the activity the record reflects and the signature or initials of the person performing the operation. All records in your HACCP plan, to comply with 21 CFR 123.8 and 21 CFR 123.10, must be verified by someone who has been trained in the application of HACCP principles. Further, to comply with 21 CFR 123.8(a)(2)(ii), you must calibrate process-monitoring instruments, including temperature-monitoring devices, on an established basis and document this calibration.

We may take further regulatory action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline specific actions you are taking to correct the deficiencies. You should include in your response documentation such as copies of HACCP plans, thermometer calibration records, receiving records, various monitoring logs, and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deficiencies.

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 applicable Current Good Manufacturing Practice regulations (21 CFR 110). You also must use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483