DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

November 13, 2008

WARNING LETTER

FEDERAL EXPRESS

Frank Cacucciolo, President
G.N.Y. Filet Fish Co., Inc.
800 Food Center Drive
Entrance C, Unit 108
Bronx, NY 10474

File No.: NYK 2009-05

Dear Mr. Cacucciolo:

We inspected your seafood processing and importer establishment, located at 800 Food Center Drive, Bronx, NY on August 28 and 29, 2008. 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 (21 CFR 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 this part, 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). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR 123. If assurances do not exist that the imported fish or fishery products have been processed under conditions equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Act, 21 U.S.C. §342(a)(4).

Accordingly, your bluefish and imported turbot 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 implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(7). However, your firm did not have any records associated with monitoring observations at the "Receiving" and "Storage" critical control points to control histamine as listed in your HACCP plan for bluefish.

2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not fulfill the affirmative step requirement for your turbot filets manufactured by [redacted] located in [redacted]

We may take further action if you do not promptly correct these violations. For instance, we may take further action to refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. §381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

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 importer verification records, records that document the performance and results of your firm's affirmative steps, HACCP and verification records associated with your activities as a domestic processor, or 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 seafood importer establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

Please send your reply to the Food and Drug Administration, Attention: Richard T. Trainor, Compliance Officer, USFDA, 300 Hamilton Ave., White Plains, NY 10601. If you have questions regarding any issues in this letter, please contact Mr. Trainor at 914-682-6166 x34.

Sincerely,

Otto D. Vitillo

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District Director