



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Atlanta District Office
HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

November 28, 2000

VIA FEDERAL EXPRESS

Harold Y. Shinn, President
Atlanta Oriental Food Wholesale, Co.
(d.b.a. Buford-Hwy Farmers Market)
5600 Buford Highway
Doraville, GA 30340

Warning Letter

01-ATL-12

Dear Mr. Shinn:

On September 18, 2000, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility located at 5600 Buford Highway, Atlanta, Georgia. During that inspection, our investigator documented serious deviations from FDA's seafood importing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause the fish and fishery products imported by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

You must implement and maintain written verification procedures to assure that the frozen fish (e.g., frozen mackerel) you offer for import have been processed in accordance with the seafood HACCP regulations, in order to comply with 21 CFR 123.12(a)(2). However, you have not established product safety specifications for the frozen mackerel, nor have you taken the appropriate affirmative step(s) to assure that it was processed under an adequate HACCP program by the foreign processor.

The deviations identified above are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products imported and distributed by your firm are in compliance with the Act and applicable regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations including an explanation of each step taken to prevent the recurrence of similar violations. 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.

Your written reply should be directed to Karen Y. Dodson, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mrs. Dodson at (404) 253-1299.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a large initial "B" and "H".

Ballard H. Graham, Director
Atlanta District