



July 14, 1999

WARNING LETTER
CHI-28-99

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eddie Chua, President
Global Marketing Enterprises, Inc.
1801-C South Canal St.
Chicago, IL 60616-1522

Dear Mr. Chua:

On April 4 and 16, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility. The inspection was made as a follow-up to our inspection and subsequent letter of July 28, 1998, concerning the new FDA Hazard Analysis Critical Control Point (HACCP) regulations for seafood. This FDA inspection was made again to evaluate HACCP requirements. At the conclusion of the inspection, you were presented with Form FDA-483, List of Observations, Form FD-3501, Domestic Seafood HACCP Report, and Form FD-3502, Importers Seafood HACCP Report. The FD-483 and FD-3502 reports describe violations to FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). By virtue of these violations, the seafood products imported by you are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigator found the following continued violations concerning requirements of 21 CFR Section 123.12:

- There was no documentation that affirmative steps were taken for the importation of Tilapia or other fish.
- There are no written specifications for Tilapia or other fish that your firm imports.

The violations cited are not all inclusive since not every product could be evaluated at the time. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct these violations. We are concerned that no corrections were made since the inspection in June 1998. Failure to promptly correct these violations may result in further regulatory action including denial of importation of the products.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps that you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We are also providing firm's the opportunity to take a HACCP refresher course, and, as discussed by the investigator during the inspection, a seminar for importers to assist in better understanding and working with the Seafood HACCP program.

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Please contact the local FDA office for further information. If you enroll in one of these courses we will extend your response time or further regulatory action provided products are not critically compromised resulting in a danger to health.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

/s/

Raymond V. Mlecko
District Director