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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FBI: 30002810361



Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 778-5454

04-BLT-03

October 29, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Tony Luu, Owner
Fortune of Seven Corners
6249 Arlington Boulevard
Falls Church, Virginia 22044

Dear Mr. Luu:

On September 23, 2003, the Food and Drug Administration's (FDA) conducted an inspection of your facility located at 6249 Arlington Boulevard, Falls Church, Virginia 22044. The inspection was conducted to determine your firm's compliance with FDA's regulations for fish and fishery products and special requirements for imported products (21 CFR 123).

During our inspection, the FDA investigator observed serious deviations from the Fish and Fishery Products regulations. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observation of concern to us was as follows:

- Fish or fishery products were obtained from a country that lacked an active memorandum of understanding or similar agreement with FDA, or no adequate written verification procedures were implemented to ensure that these fish and fishery products had been processed in accordance with 21 CFR part 123. Specifically, your firm failed to have any written verification procedures for any of the fish and fishery products imported, that is to say, no product specifications and no affirmative steps. Further, one of the products imported by your firm are live Dungeness crabs which have a natural toxin associated with them. [21 CFR 123.12(a) and (d)]

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

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include detention without physical examination and/or refusal of future entries or seizure of goods

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Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Elizabeth A. Laudig, Compliance Officer, 6000 Metro Drive, Suite 101, Baltimore, MD 21236

If you have questions regarding the implementation of the HACCP Regulations, you may contact Elizabeth A. Laudig at 410-779-5441 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,



Kirk Sooter
Acting Director, Baltimore District

Cc: Virginia Department of Agriculture
and Consumer Services
1100 Bank Street
Richmond, Virginia 23219