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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-04-23

March 16, 2004

Louis Chi, President
Maxim's Import Corporation
2719 N.W. 24th Street
Miami, Florida 33142

Dear Mr. Chi:

On November 17-20, 2003, the Food and Drug Administration (FDA) conducted an inspection of your seafood import operation, located at the above address. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis and Critical Control Point (HACCP) Regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). Under 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan complying with that section, or otherwise to 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). You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

During our inspection, the FDA investigator observed serious deviations from the special requirements for imported products specified in 21 CFR 123.12. These deviations cause the mackerel, grouper, and red snapper fishery products imported by your firm from El Salvador and Suriname to be adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4). At the conclusion of the inspection, the investigator provided you with a list of Inspectional Observations (Form FDA 483), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

You must take affirmative steps to ensure that the fish and fishery products you import are processed in accordance with the Seafood HACCP Regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform adequate affirmative steps for all fish and fishery products imported by your firm. First, your firm did not have a copy of a written HACCP plan for grouper imported by your firm from

[REDACTED] Second, although your firm maintained a copy of a written HACCP plan for red snapper imported by your firm from [REDACTED] your firm did not maintain a written guarantee from [REDACTED] as required under 21 CFR 123.12(a)(2)(ii)(D). Similar deviations were previously pointed out to your vice president, Joe L. Chi, in our letter of October 28, 1999.

Your current copy of a written HACCP plan for red snapper imported by your firm from [REDACTED] is inadequate in that it has not been reassessed or updated since May 30, 1999. Your current copy of a written HACCP plan from [REDACTED] is also inadequate in that it fails to identify the food safety hazard of scombrototoxin (histamine) formation at any of the critical control points listed in the plan as required by 21 CFR 123.6(c)(1), and the plan has not been reassessed or updated since June 1997. You should inform these foreign suppliers immediately that their HACCP plans are inadequate and not acceptable for use as your verification step.

No calibration records were available for the thermometer used to verify the cooler and freezer temperatures against the existing equipment temperature instruments. This same deviation was previously pointed out to your vice president, Joe L. Chi, in our letter of October 28, 1999. Documentation of calibration is required to be maintained by 21 CFR 123.8(d).

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, processed and distributed by your firm are in compliance with the Act and all requirements of the applicable federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating. In addition, FDA may detain your imported seafood products without physical examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any mackerel, grouper, or red snapper fishery products imported by your facility that you plan to export.

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 deviations, 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 within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. deviations,

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, you may contact Mr. Walthall by telephone at (407) 475-4731.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emma R. Singleton". The signature is written in dark ink and is positioned above the typed name.

Emma R. Singleton
Director, Florida District