



DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

January 5, 2001

Our Reference: 2939696

Mario L. Coelho, President
HGC Imports, Inc.
1045 Pepitone Avenue
San Jose, California 94110

WARNING LETTER

Dear Mr. Coelho:

We inspected your seafood firm on October 2, 2000. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your fish and fishery products, specifically refrigerated Spanish mackerel, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you and Ms. Delphine G. Coelho, Secretary-Treasurer, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your ready reference. Your serious HACCP violations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated Spanish mackerel to control the food safety hazard of histamine formation.
2. You must have written product specifications that are designed to ensure that the fish and fishery products that you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, during the inspection on October 2, 2000, we found, for example, that you did not have product specifications for refrigerated Spanish mackerel from [REDACTED] to ensure control of the potential hazard of histamine formation as a result of time/temperature abuse of the fish.
3. 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 perform an affirmative step for refrigerated Spanish

mackerel manufactured by [REDACTED]. In [REDACTED] to verify that the product was processed in accordance with the seafood HACCP regulations.

The above violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You must immediately take appropriate steps to correct these violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert, and future shipments of the product may be subject to detention without physical examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response, documentation such as copies of product specifications, your firm's HACCP plan, your foreign processor's HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Charles D. Moss
Acting Director
San Francisco District

Enclosure