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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-13

December 6, 2002

Byron Chen, President
Carib Import & Export, Inc.
3020 N. W. 75th Street
Miami, Florida 33147

Dear Mr. Chen:

We inspected your firm at the above address on September 30, 2002, and found that you have serious deviations from the U. S. Food and Drug Administration's (FDA) regulations at Title 21, Code of Federal Regulations (21 CFR), Part 123-Fish and Fishery Products (Seafood HACCP regulations). The deviations cause your refrigerated pickled vacuum packaged mackerel, pickled mackerel, smoked herring, and smoked cod to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly your refrigerated pickled vacuum packaged mackerel, pickled mackerel, smoked herring, and smoked cod are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's homepage at <http://www.fda.gov>.

The deviations are as follows:

Imports

- You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for mackerel and herring products imported from [REDACTED]. This deviation was brought to your attention in our letter to you dated August 9, 2000, and has remained uncorrected by your firm.

- 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 vacuum packaged pickled mackerel and smoked herring manufactured by [REDACTED], in [REDACTED]. This deviation was brought to your attention in our letter to you dated August 9, 2000, and has remained uncorrected by your firm.

Domestic

- 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). Your firm does not have a HACCP plan for vacuum packaged pickled mackerel to control the food safety hazards of *Clostridium botulinum* and histamines. In addition, our investigator also observed that your firm has no HACCP plans for any of the seafood products, including other mackerel products and smoked herring, which your firm sells.
- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor all eight (8) areas of sanitation with sufficient frequency to ensure control. These areas include: 1.) Safety of water; 2.) Condition and cleanliness of contact surfaces; 3.) Prevention of cross-contamination; 4.) Maintenance of hand-washing, hand-sanitizing, and toilet facilities; 5.) Protection from adulterants; 6.) Labeling, storage, and use of toxic compounds; 7.) Employee health conditions; and, 8.) Exclusion of pests. Our investigator noted that your smoked cod can be consumed without further cooking as a ready to eat, high risk product.
- You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records.

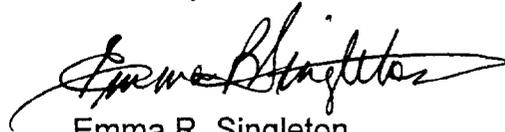
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further informal notice. For instance, we may initiate a seizure action against your aforementioned products and/or initiate an action to enjoin your firm from operating. Under such conditions, the FDA would not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District