



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-76

August 13, 2001

Ralph G. Dephoure, President
Jumpin' Jack Seafood, Incorporated
15291 N.W. 60th Avenue, #106
Miami Lakes, Florida 33014

Dear Mr. Dephoure,

We completed an inspection of your seafood importing facility, located at the above address, on May 30, 2001 and found that you continue to have serious deviations from the seafood processing (HACCP) regulations (21 CFR 123). These deviations cause your imported fresh refrigerated scombrototoxin (histamine) forming fish products such as mahi-mahi and tuna to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood processing (HACCP) regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have written product safety 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 written product specifications for fresh mahi-mahi, tuna, and all other fish and fishery products imported from Panama. This deviation was previously brought to your attention in our letter of July 13, 2000.

You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood processing (HACCP) regulations, to comply with 21 CFR 123.12 (a) (2) (ii). However, your firm did not perform an affirmative step for fresh mahi-mahi and tuna manufactured by [REDACTED]. This deviation was previously brought to your attention in our letter of July 13, 2000.

The above-identified deviations are not intended to be 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 includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will 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 notify this office in writing within fifteen (15) working days from your 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 within 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: Magda M. Karlsen, Compliance Officer, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256. If you have questions regarding the implementation of the seafood processing (HACCP) regulations, you may contact Mrs. Karlsen at 305-526-2800, extension 921, for the answers and/or directions towards guidance and sources of training in achieving compliance.

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

Sincerely,



for Emma R. Singleton
Director, Florida District