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MBC

Public Health Service

M3427A

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-00-32

February 17, 2000

Rafael Barcia, President
Lubar Seafood Corporation
8325 N.W. 30th Terrace
Miami, Florida 33122
CFN: 1058802

Dear Mr. Barcia:

On March 19 and 22, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing, processing and distributing facility located at 8325 N.W. 30th Terrace, Miami, Florida 33122. Investigator Carlos W. Hernandez documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of these deviations causes the vacuum packaged mahi mahi fillets and tuna loin products being processed and distributed by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links on FDA's Internet home page at www.fda.gov. The following deficiencies were noted:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for vacuum packed mahi mahi to control the food safety hazards of *Clostridium botulinum* toxin formation or histamine formation. Your reliance on two other plans, i.e., the vacuum packed fresh tuna loins plan for the *Clostridium botulinum* hazard and the general scombrototoxin forming fish plan for the histamine hazard, is not a satisfactory approach. A HACCP plan must be specific to each kind of fish and fishery product. Due to the nature of the toxin hazard, even frozen, vacuum packed product requires a HACCP plan to assure that conditions during the entire shelf-life of the product are controlled to prevent the formation of *Clostridium botulinum* toxin.

2. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Vacuumed Packed Fresh Tuna Loins in Plastic Bags lists a critical limit of a "maximum cooler temperature 38 degrees F" at the finished product storage critical control point. That is not in itself adequate to control *Clostridium botulinum* toxin formation. As explained to you during our inspection of your firm in July 1998 and March 1999, and in our January 8, 1999 letter to Mr. Rafael Barcia, refrigeration alone is not recognized as an adequate means of controlling *Clostridium botulinum* toxin formation in vacuum packaged refrigerated raw fish. Your firm should provide evidence to demonstrate that conditions during the entire shelf-life of the product, including storage, distribution, retail display, and general consumer handling are controlled to preclude the formation of *Clostridium botulinum* toxin. Freezing of the vacuum packaged raw product immediately after processing, and labeling the product appropriately, e.g., "Important - Must Be Kept Frozen," may be considered as an alternative.

3. You must implement the record keeping system listed in your HACCP plan in order to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving critical control point to control scombrotoxin formation in your HACCP plan for histamine producing fish. Specifically, your receiving records for tuna received on July 10, 1998 and August 25, 1998 do not document internal fish temperatures or the adequacy of ice or chemical coolant per your HACCP plan. Also, during our inspection, your firm was observed to have failed to record internal fish temperatures upon receipt of mahi mahi on March 19, 1999 for P.O. #73170. Your firm inappropriately measured internal fish temperatures and recorded values on the receiving record after the product had already moved to another critical control point, cooler storage. This too was inconsistent with your plan and is an inadequate means of assessing temperature control of the fish during shipment to your facility.

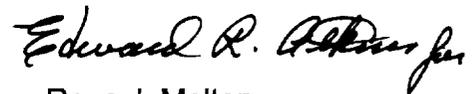
The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

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 includes seizure and/or injunction or removal from the European Union (EU) list. In addition, until FDA is satisfied that the above deficiencies have been corrected, we may not provide certificates to your firm for export of your products to EU countries.

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

Your written reply should be directed to Benjamin L. England, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward R. Melton". The signature is written in a cursive style with a large, stylized initial "E".

Reva J. Melton
Acting Director
Florida District