



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER

FLA-03-34

June 17, 2003

Milton L. Mecozzi Sr., President
Bobbery Enterprises, Incorporated
P.O. Box 160460
Miami, Florida 33016

Dear Mr. Mecozzi:

On January 15-17, 2003, the Food and Drug Administration, (FDA) conducted an inspection of your seafood import operation located at 2760 West 81 Street, Hialeah, Florida. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulations, 21 CFR 123, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products", and the Good Manufacturing Practices (GMP) requirements for foods, 21 CFR Part 110. The Seafood HACCP Regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulations is adulterated, according to the Act, because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at <http://www.fda.gov>.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as HACCP. HACCP involves:

- (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and
- (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrate to FDA, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During our inspection, the FDA investigator observed shortcomings in your import verification procedures that, upon our preliminary review, appear to be deviations from the requirements of the Seafood HACCP Regulations. Our investigator also provided your vice-president, Milton L. Mecozzi Jr., 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 have written 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's written product specifications for imported Tuna does not include a written product specification for histamines. This same deviation was previously brought to your attention in our letter of June 2, 1999.

You must maintain records, in English, that document the performance and results of the affirmative steps chosen by your firm, to comply with 21 CFR 123.12(c). Your firm has chosen to obtain the foreign manufacturer's HACCP plan and written guarantee as part of your affirmative steps to satisfy the requirements of 21 CFR 123.12(a)(2)(ii). However, your firm did not have a copy of a HACCP plan and written guarantee, in English, for Tuna manufactured by Agrol S.A. in Ecuador and imported into the U.S. by your firm. A similar deviation was previously brought to your attention in our letter of June 2, 1999.

We acknowledge receipt of your written response to the FDA 483 dated February 26, 2003. The enclosed copy of the written guarantee from Agrol S.A. in Ecuador appears adequate. However, a copy of their HACCP plan, in English, and a copy of your revised written product specifications were not included for review. This response does not alleviate all of our concerns regarding the observations made during our inspection.

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 Food, Drug, and Cosmetic Act (the Act) and all requirements of the federal regulations.

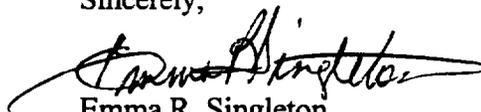
These deviations cause your imported Tuna from Ecuador to be adulterated within the meaning of Section 402(a)(4) of the Act 21 U.S.C. 342(a)(4). You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as 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 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.

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

Emma R. Singleton
Director, Florida District