



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

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

VIA CERTIFIED MAIL

WARNING LETTER

FLA-04-12

January 7, 2004

Robert G. Meeks, Jr.
Owner, President and General Manager
Royalty Foods, Inc.
6831 Narcoossee Road
Orlando, Florida 32822

Dear Mr. Meeks:

We inspected your firm, at the above address, on August 14 and 20, 2003, and found that you have serious deviations from the Seafood HACCP regulation, Title 21, Code of Federal Regulations (21 CFR), Part 123. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with 21 CFR Part 123 or otherwise operate in accordance with the requirements of this part renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your fishery products are adulterated, in that the ready-to-eat fishery products such as canned pasteurized crabmeat, caviar and seafood base 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 and the Seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

During our inspection, the investigator provided you with a list of Inspectional Observations (Form FDA 483), which presents her evaluation of your firm's performance regarding various aspects of the HACCP requirements. We acknowledge receipt of your firm's written responses, dated October 16, 2003 and November 3, 2003, in reply to the untitled letter we sent your firm on June 19, 2003, and to the current inspection concluded on August 20, 2003. These responses have been reviewed and will be made part of the official file. It appears that you are taking steps to bring your firm into compliance with the seafood HACCP regulations. However, your responses are only partially adequate, because they do not alleviate all of our concerns. Specifically, they do not address how you will remedy the following deviation:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and 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(a) and (b). However your firm's hazard analysis for refrigerated fishery products fails to identify Receiving and Refrigerated Storage as critical control points. Accordingly, your firm has not properly established and has not implemented a HACCP

plan for your ready-to-eat fishery products, such as canned pasteurized crabmeat and caviar, to control the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum*. In addition, your firm does not have a HACCP plan for refrigerated seafood base products received by your firm such as shrimp, clam, and lobster bases to control the food safety hazard of pathogen growth and toxin formation.

In addition, your responses do not address observations pertaining to herring fillets in wine sauce observed during our inspection. You should confirm whether this product has been discontinued.

We agree with your response that fishery products that are received, stored, and shipped frozen do not have any food safety hazards reasonably likely to occur.

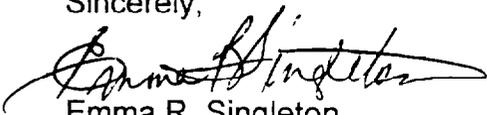
We may take further action if you do not promptly correct these violations. For instance, we may take steps to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as new or revised HACCP plans and completed monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all of 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 Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari H. Shambaugh, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mrs. Shambaugh at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", written over a horizontal line.

Emma R. Singleton
Director, Florida District