



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94524d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

February 3, 2004

Our Reference: FEI 3003236744

Tonia A. Onuegbe, Owner  
Zuka Trading and Distribution Company  
1780 "H" Old Bayshore Highway  
San Jose, California 95112

**WARNING LETTER**

Dear Ms. Onuegbe:

We inspected your seafood firm on October 31, 2003 and November 3, 2003. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123. The Seafood Hazard Analysis and Critical Control Point (HACCP) Regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). You can find this Act and the Seafood HACCP Regulation through links in FDA's home page at <http://www.fda.gov>.

We found that your firm has a serious HACCP deviation. This deviation causes your Dried Cod Fish to be adulterated within the meaning of Section 402(a)(4) of the Act 21 U.S.C. § 342(a)(4), in that the fish had been prepared, packed, or held under insanitary conditions, whereby it may have been rendered injurious to health. We listed the HACCP deviation on a Form FDA 483 and discussed it with you, at the conclusion of the inspection. Your serious HACCP deviation was:

You must have product specifications that are designed to ensure that 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 Dried Cod Fish imported from Canada.

The above-identified deviation is 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 the requirements of the federal regulations.

You should take prompt measures to correct the deviation. Failure to promptly correct the deviation noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafoods without examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct the violation, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen  
Acting District Director  
San Francisco District