



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M29320

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

VIA FEDERAL EXPRESS

Our Reference Number: 2936930

September 9, 1999

Tim M. Oftana, Owner
Guam Bakery
136-A Kayen Chando
Dededo, GU 96912

WARNING LETTER

Dear Mr. Oftana:

On August 6 and 11, 1999, FDA Investigator Lorna F. Jones conducted an inspection of your bakery located at 136-A Kayen Chando, Dededo, Guam, 96912. Your operations at this site are in serious violation of the federal regulations for good manufacturing practices (GMP's) which are established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110), Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act. Observations by FDA Investigator Jones were listed on Form FDA 483, List of Inspectional Observations; a copy was provided to and discussed with you at the conclusion of the inspection.

The following observations demonstrate that your facility does not adequately protect food from possible contamination: The potable water lines inside the food preparation area lack back flow prevention devices. An employee was observed handling garbage and then handling the dough, without washing his hands between these separate operations. The dough molder machine has flour build-up from the previous day, and the machine is being used the next day without cleaning prior to use. The three-compartment sink for pots and pans is not adequately drained. Soiled wiping cloths with grease and food debris build-up are stored inside the food preparation area. Raw foods, including trays of apple turnovers, were stored inside the dry goods area without any covering.

Based on these findings, your operation has been assessed a rating score of 59% and given a "Provisional" classification, as indicated on the Form FDA 2420, Food Service Establishment Inspection Report (a copy of which was provided to you at the end of the inspection). A classification of "Provisional" means that, if the violations are not corrected within thirty (30) working days from receipt of this notification, your firm may be placed on "NOT APPROVED", use prohibited status. "NOT APPROVED" means that food and beverages from your firm may not be used on interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

These insanitary conditions are likely to result in adulteration of foods within the meaning of Sections 402(a)(3) and/or 402(a)(4) of the Food, Drug and Cosmetic Act. Adulteration of food while held for

sale after shipment in interstate commerce is prohibited by Section 301(k) of the Act. Delivery of, or causing the delivery of adulterated foods into interstate commerce is prohibited by Section 301(a).

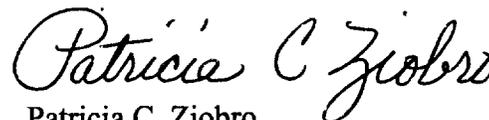
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations.

You should take prompt action to correct these deficiencies. Failure to do so may result in appropriate regulatory action, such as seizure and/or injunction without further notice. You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of preventive measures taken to preclude recurrence of similar violations. If corrective action cannot be completed within fifteen working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent to:

Randall P. Zielinski, CSO/ITS
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,



Patricia C. Ziobro
Director
San Francisco District

Enclosures:

FDA 2420 Food Service Establishment Inspection Report, dated August 11, 1999
FDA 483, Inspectional Observations, dated August 11, 1999

Cc: Annabelle L. Cruz
Chief
Department of Public Health & Social Services
Division of Environmental Health
P.O. Box 2816
Hagatna, Guam 96932