



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g4303d

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

Via Federal Express

Our Reference: 2936930

September 17, 2003

Anthony H. Oftana  
General Manager  
Guam's Bakery, Inc.  
136-A Kayen Chando  
Dededo, GU 96929

**WARNING LETTER**

Dear Mr. Oftana:

Between July 29 and 31, 2003, FDA conducted an inspection of your facility located at 136-A Keyen Chando, Dededo, Guam, which provides food service to [REDACTED]. The observations made during the inspection revealed that your facility is in violation of the Public Health Service Act, and its implementing regulations for "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" and "Interstate Conveyance Sanitation" (Title 21, Code of Federal Regulations, Parts 110 and 1250). FDA's observations were listed on Form FDA 483, List of Inspectional Observations, a copy of which was provided to and discussed with you at the conclusion of the inspection.

During the inspection the following observations were noted:

1. The receiving door to the back storage area was left open and a stray dog was observed licking sugar from the top of a pallet of sugar; flies were observed on each of five pallets of stored flour and sugar; and dark brown foreign objects that appeared to be rodent pellets were observed on the top of four bags of sugar (21 CFR 110.35(c)).
2. Employees were observed wiping perspiration from their foreheads with their hands and/or forearms and then proceeding to work with dough and/or equipment without washing their hands/forearms (21 CFR 110.10(b)(9)).
3. An employee was observed wearing a wrist-watch, that contained flour dust, while kneading raisin bread dough (21 CFR 110.10(b)(4)).

4. Residues of rust were observed on the inside of an ice machine (21 CFR 110.35(d)).
5. The employee's hand washing sink in the packaging room lacked sanitary towels or a hand drying device (21 CFR 110.37(e)(3)).
6. The employee's restrooms lacked soap and sanitary towels or hand drying devices (21 CFR 110.37(d)(1)).
7. The employee's restrooms had leaking water pipes which were flooding the bathroom floors (21 CFR 110.37(d)(2)).
8. No chemical strips/kits were available to test the sanitation rinse water for growth of undesirable microorganisms (21 CFR 110.80).
9. Old food residue build-up was observed in the gaps between bread baking pans (21 CFR 110.35(d)(3)).

These insanitary conditions are likely to result in adulteration of food within the meaning of Sections 402(a)(3) and 402(a)(4) of the Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 342(a)(3) and (4). Adulteration of food while held for sale after shipment in interstate commerce is prohibited by Section 301(k) of the Act, 21 U.S.C. § 331(k). The delivery of or causing the delivery of adulterated foods into interstate commerce is prohibited by Section 301(a), 21 U.S.C. § 331(a).

The list of inspectional observations, identified above, is not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the regulations.

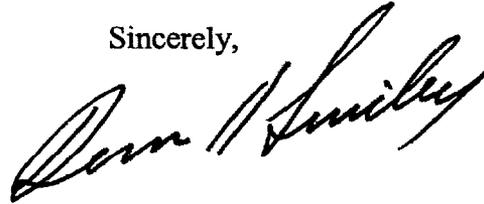
Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use for a period of thirty (30) days. A "Provisional" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made by the time of the next inspection, this facility will be reclassified as "Not Approved" for carrier use. Assignment of "Not Approved" status for food service facilities means that food and beverages from this facility may not be used by interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps that you have taken to prevent a recurrence of the cited deficiencies. Your response should include a discussion of any delays you foresee in achieving correction, and a deadline by which correction can be expected. Your response should be directed to:

Randall P. Zielinski  
Interstate Travel Specialist  
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,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosures:

Form FDA 483, Inspectional Observations, dated 7/31/03.  
Form FDA 2420, Food Service Establishment Inspection Report