



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91673d

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 22, 2001

W/L 74-01

Juliet M. Villamor, Owner
Zambales Bakery and Fast Food
11271 Camino Ruiz
San Diego, CA 92126

Dear Ms. Villamor:

On May 18 - 21, 2001, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of Zambales Bakery and Fast Food, located at the above address. At the conclusion of the inspection, you were presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products Regulation. By reason of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402 (a) (4) of the Food, Drug and Cosmetic Act (the Act).

Our investigator found the following deficiencies related to ready-to-eat cooked eviscerated fish as a refrigerated product:

1. Monitoring procedures listed in your HACCP plan were not followed as required by 21 CFR 123.6(b). Specifically, during your processing of product on May 18, 2001, you did not record the monitoring data for the cooking critical control point as required by your HACCP plan. A review of your firm's records showed you were only recording data once during a day's production and not at each cook as required by your HACCP plan.
2. Your HACCP plan does not list all of the critical control points for each identified food safety hazard as required by 21 CFR 123.6(c)(2). Specifically, your HACCP plan fails to identify "Storage of the Finished Product" as a critical control point for the hazard of pathogen growth after cooking. The storage of the cooked smoked flavored fish prior to distribution must be controlled and monitored to ensure that pathogens may not form due to temperature abuse.

3. You have failed to maintain sanitation control records that document sanitation monitoring in your firm as required by 21 CFR 123.11(c). Specifically, other than the cleaning of food contact surfaces, you are not recording the key sanitation conditions and practices listed in 21 CFR 123.11(b).
4. Your HACCP plan includes a corrective action that was not developed in accordance with 21 CFR 123.7(b). Specifically, the corrective action for a deviation from the critical limits for the product cook does not ensure that the cause of the deviation is corrected nor that the product failing to meet the critical limits will not enter commerce.

In addition to these observations listed on the form FDA 483 and discussed with you at the conclusion of the inspection, our review of the Scad, Milk Fish, Butter Fish Tinapa product labels collected at the time of the inspection reveals that these products are in violation of section 403 of the Act and 21 CFR Part 101 - Food Labeling as follows :

5. These products are misbranded in that they fail to bear the name and place of business of your firm as required by section 403(e)(1) of the Act and 21 CFR 101.5. You have not listed your firm's street address (unless your are listed in a current city directory or phone book), city, state, and zip code.
6. These products are misbranded in that they fail to bear an adequate declaration of the certifiable foods colors FD&C Yellow No. 5 and 6 as required by 403(k) of the Act and 21 CFR 101.22(k). It is not necessary to include the "FD&C" prefix or the term "no." in the declaration but the name of the color must be complete (e.g. yellow 5, or yellow 6).

We acknowledge your June 4, 2001 revisions to the monitoring record and HACCP plan. After review we find it inadequate. For example, the corrective action listed for the cooking step does not address the reason why the oven was not at the proper temperature or the time of the cook was less than required. Corrective actions must follow the procedures of 21 CFR 123.7(c), which requires correction of the cause of the deviation. Your HACCP plan also states that the verification record will be the monitoring record. The monitoring record does not provide a place for such an entry.

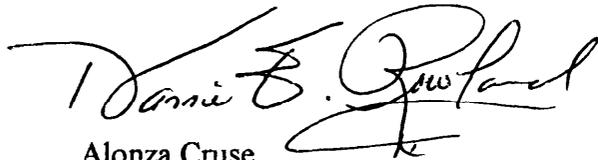
The violations listed above are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all your products comply with the requirements of the Act and its implementing regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to:

Mr. Thomas L. Sawyer, Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza Cruse". The signature is fluid and cursive, with a large initial "A" and a long, sweeping underline.

Alonza Cruse
Los Angeles District

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief