



DEPARTMENT OF HEALTH & HUMAN SERVICES

94470d

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

December 17, 2003

Jacinto B. Badua, President  
Jesse's Bakery, Inc.  
P.O. Box 6459  
Honolulu, Hawaii 96818

**WARNING LETTER**

Dear Mr. Badua:

On July 23, 25, and 29, 2003, an investigator from the Food and Drug Administration conducted an inspection of your manufacturing facility, located at 1064 Valkenburgh Street, Honolulu, Hawaii. During the inspection, the investigator collected labels of three products that your firm manufactures and distributes for wholesale or retail sale:

- BALINTAWAK (Pastry Slices),
- PAN DE COCO (Coconut Rolls), and
- PAN DE SAL (Spanish Rolls)

Our review of your labels and production facilities found your products to be adulterated and misbranded under Sections 402(a)(4), 403(i)(2), and 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations contained within Title 21, Code of Federal Regulations (CFR). You can find copies of the Act and food regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

FDA observed a number of gross unsanitary conditions present in your facility at the time of inspection. These conditions caused products manufactured in your facility at that time to be adulterated within the meaning of Section 402(a)(4) of the Act. The following is a list of the unsanitary conditions observed by our investigator during the inspection:

- Failure to take effective measures to exclude pests from the processing areas as per 21 CFR 110.35(c). For example, a live mouse was observed under the three-compartment sink; a live rat was observed running across the floor while your firm was processing; at least seven live cockroaches were observed as bags of flour were removed from pallets; two live cockroaches and one dead cockroach were observed in the three-compartment sink; a live cockroach was observed on

the wall by the office; and at least 50 live ants were observed behind the mixer along the wall.

- Failure to provide adequate screening or other protection against pests as per 21 CFR 110.20(b)(7). For example, a half inch gap was observed between the floor and the door leading from the manufacturing area to the outside.
- Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms or foreign substances as per 21 CFR 110.10(b)(9). Specifically, an employee was observed scraping batter off the floor with a metal hand scraper. The same scraper was later seen used to scrape built-up batter from the commercial mixer that was being used to mix batter.
- Failure to maintain food contact surfaces to protect food from being contaminated as per 21 CFR 110.40(a). Specifically, commercial mixer parts, bowls, and metal hand scrapers had dirt and ingredient buildup that appeared to be from one or more days of use.

We acknowledge that your firm hired the services of [REDACTED] to address your pest problems, that your firm began a clean-up of the facility and equipment during our inspection, and that you committed to arrange for your employees to take a sanitation course offered by the Hawaii Food and Drug Branch Sanitation Specialist.

During a review of the labeling for your products, we noted the following:

1. Your Balintawak (Pastry Slices) product is misbranded under Section 403(i)(2) of the Act because it contains a certified color additive, FD&C Red No. 3, but its label fails to list this ingredient by name. 21 CFR 101.22(k)(1) requires that a color additive subject to certification shall be declared by the name of the color additive listed in its applicable listing regulation, in this case §74.303, FD&C Red No. 3. The declaration may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Red 3). Our inspection revealed that Balintawak is formulated using "Pink Liquid Color," the label of which declares the presence of FD&C Red No. 3. Analysis of your product completed by an FDA laboratory confirmed the presence of this colorant.
2. Your Balintawak, Pan de Coco, and Pan de Sal products are misbranded within the meaning of section 403(q)(1) of the Act in that the labels fail to bear nutrition information as required by 21 CFR 101.9.

In lieu of adding nutrition information to the labels of these products, you may be eligible to claim an exemption from the nutrition labeling requirement under the small business exemption (see 21 CFR 101.9(j)(18)). This exemption is based on the number of employees and the number of product units sold annually. The exemption applies to a food product if fewer than 100,000 units of the product were sold in the United States during the preceding 12 months and if the business claiming the exemption employed fewer than an average of 100 full-time equivalent employees during that time period. A

firm claiming this exemption must file an annual notice with the Food and Drug Administration. To claim this exemption, follow the procedure outlined in 21 CFR 101.9(j)(18)(ii) and (iv) ([www.cfsan.fda.gov/~lrd/CFR101-9.html](http://www.cfsan.fda.gov/~lrd/CFR101-9.html).) The form used to claim an exemption is available on the Internet at [www.cfsan.fda.gov/~dms/sbelform.html](http://www.cfsan.fda.gov/~dms/sbelform.html). See attached handout on the Small Business Food Labeling Exemption.

3. Your Pan de Coco product is misbranded under Section 403(i)(2) of the Act because the common or usual names of all ingredients are not declared on the label. The product label declares "shortening", but does not specify the type of shortening (e.g., Vegetable shortening (soybean and cottonseed oil)) as required by 21 CFR 101.4(b)(14).

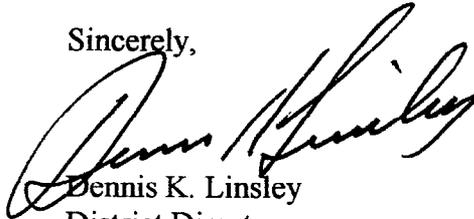
The above violations are not meant to be an all-inclusive list of violations at your firm. You are responsible for ensuring that your processing facility operates in compliance with the Act and FDA regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. It has been five months since the completion of our inspections, which should have afforded you ample time to make corrections to the observations which were summarized on the Form FDA 483 issued to Mr. Manuel A. Badua. You may wish to include in your response documentation 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 your delay, and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosure: Handout on Small Business Food Labeling Exemption