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



DEPARTMENT OF HEALTH & HUMAN SERVICES

VIA FEDERAL EXPRESS

Our Reference: 2938133

February 12, 2003

Charles A. Higa, Vice President  
FCH Enterprises Inc. dba Napoleon's Bakery  
1765 S. King Street  
Honolulu, Hawaii 96826

**WARNING LETTER**

Dear Mr. Higa:

On August 20, 21, and 23, 2002 and on September 17 and 19, 2002, we inspected your manufacturing facility, located at 94-1068 Ka-Uka Blvd., Waipahu, HI. During the August inspection, we noted that packaged cakes and other bakery products distributed for institutional sale bear no label information. These products are misbranded under sections 403(i)(1), 403(i)(2), 403(e)(1), and 403(e)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the product label fails to declare the common or usual name of the food; the common or usual name of each of the ingredients; the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, respectively. Undeclared ingredients in these products include wheat flour and eggs, which are known allergens. Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.

Additionally, during the September inspection, we collected samples of Blueberry Hawaiian Bagel. Our label review and sample analysis for this product found that it is misbranded under Section 403 of the Act as follows:

1. The product is misbranded within the meaning of section 403(i)(2) of the Act because it contains certified color additives that are not declared in the ingredient statement. Under section 403(i)(2) of the Act and Title 21, Code of Federal Regulations, section 101.22(k)(1) [21 CFR 101.22(k)(1)], color additives and the

lakes of color additives subject to certification must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Blue No. 1 Lake, FD&C Red No. 40 Lake, FD&C Red No. 3). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Red 3), but the term "Lake" must be included in the declaration of the lake of a certified color additive (e.g., Blue 1 Lake, Red 40 Lake).

2. Additionally, the Blueberry Hawaiian Bagel is misbranded within the meaning of section 403(a)(1) of the Act in that the label is false or misleading. While the statement of identity implies that the product is made with blueberries, our inspection revealed that the bagels do not contain blueberries but rather are made with artificially blueberry flavored apples.

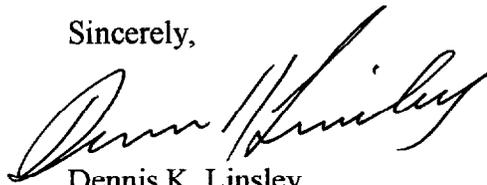
The above labeling violations are not meant to be an all-inclusive list of all of the deficiencies of your food products. It is your responsibility to ensure that all your products meet the requirements of all applicable laws and regulations.

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.

Almost five months have elapsed since FDA inspection. Please provide a response in writing within fifteen (15) working days of receipt of this letter of the steps your firm has taken to correct the above-listed violations. 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.

Your response should be directed 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

cc: Jan M. Tsukazaki, Plant Manager  
FCH Enterprises Inc. dba Napoleon's Bakery  
94-1068 Ka-Uka Blvd.  
Waipahu, HI 96797