



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

VIA FEDERAL EXPRESS

Our Reference: 2923354

January 30, 2003

Mr. Aaron A. Lee
Shiro and Associates
98-020 Kamehameha Highway
Aiea, Hawaii 96701

WARNING LETTER

Dear Mr. Lee:

On July 11, 12, 15 & 16, 2002 and October 2, 2002, we inspected your manufacturing facility, Five Star Noodle Factory, located at 2003 Colburn Street, Honolulu, Hawaii. This Warning Letter is based on evidence from both the July and October inspections.

1. During the inspections, we collected samples of your raw 'frying noodle' product that you manufacture and distribute. Our review of the labels and labeling for the 'frying noodle' product found that it is adulterated under section 402(c) of the Act because the product contains FD&C Yellow No. 5, and the presence of that ingredient is not declared on the product's label. You must specifically declare the presence of FD&C Yellow No. 5 in the ingredient statement on your product's label to comply with Title 21, Code of Federal Regulations, Part 74.705(d)(2)—21 CFR 74.705(d)(2). The declaration of FD&C Yellow No. 5 as an ingredient is a condition for safe use of this color additive in food products.
2. Your 'frying noodle' product is also misbranded under sections 403(i)(2) and 403(k) of the Act because it contains certified color additives (FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40) that are not declared on the product's labels. Under 21 CFR 101.22(k)(1), certified color additives must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Yellow No. 5, FD&C Yellow No. 6, and FD&C Red No. 40). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 5, Red 40).

3. Your “saimin,” “udon,” and “fried” noodle products sold in bulk to restaurants are misbranded under:
- 403(i)(1) for failure to declare the common or usual name of the food as required by 21 CFR 101.3,
 - 403(i)(2) for failure to declare the common or usual name of their ingredients as required by 21 CFR 101.4, and
 - 403(e)(1) for failure to declare the name and place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5.

In accordance with 403(e) and 403(i), products in package form that are intended for institutional use (e.g., use by hotels and restaurants), at a minimum, must bear the above required label information.

The declaration of wheat flour, an ingredient in your “saimin,” “udon,” and “frying” and “fried” noodle products is of particular concern because it is an allergenic substance. 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 know to cause serious allergenic responses are milk, eggs, fish, crustacean, tree nuts, wheat, peanuts, soybeans, and derivatives of the these products.

4. Your wun tun pi product is misbranded under section 403(e)(1) of the Act because its label does not declare the place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5.

As a manufacturer of products regulated by the Food and Drug Administration, you are responsible for ensuring that your processing facility operates in compliance with all provisions of the Act and all applicable 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 four months have elapsed since FDA inspection. Please provide a response in writing within fifteen (15) working days of receipt of this letter, stating the actions you plan to take, or have taken, to correct all violations. Your response should outline the specific things you are doing to correct the deviations. 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