



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration 94009

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2919928

April 24, 2003

Arthur M. Uyehara, Manager
All Island Saimin LLC
P.O. Box 22750
Honolulu, Hawaii 96823

WARNING LETTER

Dear Mr. Uyehara:

On November 27, 29 and December 3, 5, 10, and 11, 2002, we inspected your manufacturing facility, All Island Saimin LLC, located at 718A Bannister Street, Honolulu, Hawaii. During the inspection, we collected labels of products that your firm manufactures and distributes for retail sale and wholesale distribution. Our label review revealed that your saimin and soba products are in violation of sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101—Food Labeling, as follows:

1. Saimin
 - a. Your retail packages and wholesale cartons (i.e., the bulk containers) of “Saimin” are misbranded under section 403(i)(2) of the Act in that the ingredient statement fails to declare all of the ingredients in the food by their common or usual name as required by 21 CFR 101.4. Your “Saimin” product contains enriched flour, a food for which a standard of identity has been established in 21 CFR 137.165, but it is not declared as “enriched flour” as required by 21 CFR 101.4(a)(1). Furthermore, the ingredient statement fails to declare all of the ingredients in the enriched flour (e.g., flour, niacin, iron, thiamin mononitrate, riboflavin, and folic acid) as required by 21 CFR 101.4(b). Additionally, the ingredient statement for the wholesale cartons (i.e., the bulk containers) of “Saimin” product formulated with nori (seaweed) fails to list this ingredient.
 - b. Your wholesale cartons (i.e., the bulk containers) of “Saimin” are misbranded under section 403(e)(2) of the Act in that they fail to declare

an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count as required by 21 CFR 101.105.

2. Soba

- a. Your "Soba" product in wholesale cartons (i.e., the bulk containers) is adulterated under section 402(c) of the Act because FDA laboratory analysis found that 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 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.
- b. Your wholesale cartons (i.e., the bulk containers) of "Soba" are misbranded under section 403(i)(2) of the Act in that the ingredient statement fails to declare all of the ingredients in the food by their common or usual name as required by 21 CFR 101.4. Your "Green Soba" product contains enriched flour, a food for which a standard of identity has been established in 21 CFR 137.165, but it is not declared as "enriched flour" as required by 21 CFR 101.4(a)(1). Furthermore, the ingredient statement fails to declare all of the ingredients in the enriched flour (e.g., flour, niacin, iron, thiamin mononitrate, riboflavin, and folic acid) as required by 21 CFR 101.4(b). Additionally, the ingredient list fails to declare the ingredient buckwheat flour.
- c. Your wholesale cartons (i.e., the bulk containers) of "Soba" are misbranded under sections 403(i)(2) and 403(k) of the Act because the product contains certified color additives (FD&C Blue No. 1 and FD&C Yellow No. 5) which 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 Blue No. 1 and FD&C Yellow No. 5). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term No. (e.g., Blue 1, Yellow 5).
- d. Your wholesale cartons (i.e., the bulk containers) of "Soba" are misbranded under section 403(e)(2) of the Act in that the cartons fail to declare an accurate statement of the quantity of contents in terms of weight, measure, or numerical count as required by 21 CFR 101.105.
- e. Your wholesale cartons (i.e., the bulk containers) of "Soba" are misbranded under section 403(b) of the Act in that the product is being offered for sale under the name of another food, i.e., it is sold in cartons labeled "Saimin." The product is also misbranded under section 403(i)(1) of the Act and 21 CFR 101.3 because the food is not identified

on the wholesale cartons (i.e., the bulk containers) by its common or usual name.

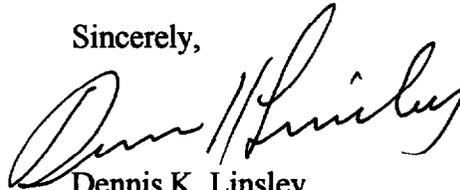
The above violations are not meant to be an all-inclusive list of deficiencies of your products. Other violations, including other label violations, can subject the foods to legal action. It is your responsibility to ensure that all of your products are manufactured and labeled in accordance with applicable statutes 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.

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 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