



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93514d

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

VIA FEDERAL EXPRESS

Our Reference: 2956205

September 24, 2002

Jiri Knedlick, Co-Owner
Sacramento Cookie Factory
3428 Auburn Boulevard
Sacramento, CA 95821

WARNING LETTER

Dear Mr. Knedlick:

On April 17 and 18 and June 4 and 5, 2002, we inspected your manufacturing facility, located at 3428 Auburn Boulevard, Sacramento, CA. During the inspection, we collected samples of Lemon Almond Wafer Cookies that you manufacture and distribute. Our label review and sample analysis for this product found violations of Sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

The product "Lemon Almond Alaska Wafer Cookies" is adulterated under section 402(c) of the Federal Food, Drug, and Cosmetic Act (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.

The product is also misbranded under section 403(i)(2) of the Act because the product contains certified color additives that are not declared in the ingredient statement. Under section 403(i)(2) and 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 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).

FDA observed a number of insanitary conditions present in your facility at the time of inspection. These conditions cause products manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Act.

The insanitary conditions are as follows:

1. Failure to maintain equipment in an acceptable condition through appropriate cleaning, as necessary (see 21 CFR 110.80(b)(1)). Specifically, FDA observed a build-up of old cookie dough on vinyl sheets between cookie hot presses.
2. Failure of personnel to wear hair nets or other hair restraints (see 21 CFR 110.10(b)(6)). Specifically, FDA observed that you were pressing cookie wafers without wearing any type of hair covering.

FDA investigation found that you had distributed a number of misbranded and adulterated products that did not declare the presence of certified color additives, e.g., FD&C Yellow No. 5 and FD&C Red No. 40. You refused to recall the misbranded and adulterated products. The introduction or delivery for introduction of an adulterated or misbranded food into interstate commerce is a violation of section 301(a) of the Act. You are responsible for ensuring that your processing facility operates in compliance with all provisions of the Act.

At the conclusion of the inspection, the investigator's observations were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference.

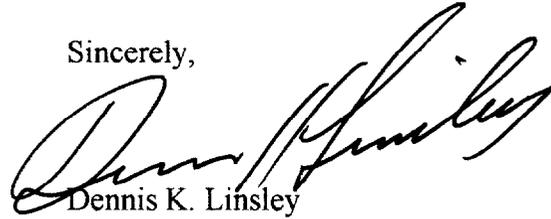
The violations listed above are not meant to be an all-inclusive list of deficiencies in your product labeling or at your facility. It is your responsibility to ensure that all of your products are manufactured and labeled in accordance with applicable statutes and regulations.

Over three months have elapsed since FDA inspection which should have been sufficient time to correct the above violations. We may take further action if you have not corrected 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 violations listed above. 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 violations.

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,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, with a large initial "D" and "L".

Dennis K. Linsley
District Director
San Francisco District

Enclosure:
Form FDA 483