



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94011d

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

VIA FEDERAL EXPRESS

Our Reference: 2910217

April 29, 2003

George A. Bezzerides, President
Bezzerides Co.
398 West Channel Road
Benicia, California 94510-0825

WARNING LETTER

Dear Mr. Bezzerides:

On December 10, 2002, we inspected your manufacturing facility located at 398 West Channel Road, Benicia, CA. During the inspection, we collected samples of California Mix that you manufacture and distribute. Our label review and sample analysis for this product found violations of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

1. The product is misbranded under section 403(i)(2) and 403(k) of the Act because it contains a certified color additive, FD&C Yellow No. 6, that is not declared in the ingredient statement. Under Title 21, Code of Federal Regulations, Part 101.22(k)(1), [21 CFR 101.22(k)(1)], color additives subject to certification must be individually declared in the ingredient statement by the name specified in the color additive regulation (e.g., FD&C Yellow No. 6). The name may be abbreviated to omit the FD&C prefix and the term "No." (e.g., Yellow 6).

We acknowledge that within a week of our December 10, 2002 inspection, you contacted your supplier and exchanged your stock of dehydrated papayas containing FD&C Yellow No. 6 for papayas without FD&C Yellow No. 6. However, even though FDA advised you on December 10, 2002 of the undeclared color additive in the dehydrated papaya in your California Mix product, you distributed cases containing packages of 2.5 oz. bags of California Mix that were manufactured on that date; and you did not initiate a recall when FDA contacted you on December 11, 2002 to determine your intention with respect to the disposition of this product.

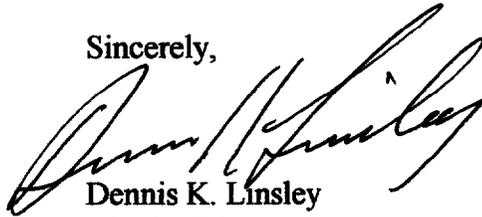
The violations listed above are not meant to be an all-inclusive list of deficiencies in your product labeling. It is your responsibility to ensure that all of your products are manufactured and labeled in accordance with applicable statutes and regulations.

We may take further action if you do not prevent these violations from recurring in the future. 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

cc: Arthur A. Bezzerides, Secretary-Treasurer