



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
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January 25, 2001

WARNING LETTER NO. 2001-NOL-08

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Maxmillan H. Burnell
President and CEO
Kiko Foods Inc.
2628 Lexington Avenue
Kenner, LA 70062

Dear Mr. Burnell:

On July 25, 2000, an investigator of the U.S. Food and Drug Administration (FDA) collected a sample of Enriched Fruit Juice Drink (Punch) from your facility, located at 5510 Jefferson Highway, Jefferson, Louisiana. During a follow-up inspection, on August 17, 18, 23, 25, 30 & September 7, 2000, another FDA investigator collected various samples of your fruit-flavored drinks.

Samples of your various fruit-flavored drinks were assayed for Vitamin C content, per AOAC, 16th Edition, Official Method 967.22, by the FDA Southeast Regional Laboratory; and two of your products were found to be below the declared percentage of Vitamin C per the respective finished-product label. For this reason, your products, Kiko's Shazam Grape Enchantingly Fruity Drink and Kiko's Alakazam Apple Enchantingly Fruity Drink, are misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

Also, your product, Pak-A-Punch Fruit Punch, is misbranded within the meaning of Section 403(i)(2) of the Act because the label does not bear a statement of the total percentage of juice (21 CFR 101.30). In addition, FDA has additional comments regarding your Pak-A-Punch Fruit Punch product. They are as follows:

- The label for Pak-A-Punch Fruit Punch bears a vignette of a pear but the product does not contain pear juice; and,
- The units of measure for total carbohydrates on the nutrition facts label of Pak-A-Punch Fruit is declared in milligrams instead of grams [21 CFR 101.9(c)(6)].

The above is not intended to be an all-inclusive citation of deficiencies at your facility. It is your responsibility to assure that your processing plant is operating in compliance with applicable requirements and regulations and to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problem(s). Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We are aware that on September 11, 2000, you made a commitment to correct the sample test result/finished product labeling discrepancies. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time by which corrections will be completed. Once corrective actions have been taken, forward to this office documentation necessary to verify corrections have been achieved.

Your reply should be directed to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have questions concerning the contents of this letter, you may contact Ms. Asente at (504) 253-4519.

Sincerely,


Carl E. Draper
District Director
New Orleans District