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19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

June 18, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David Fox, Owner
Orange Bang, Inc.
13115 Telfair Avenue
Sylmar, CA 91342

W/L 34-9

Dear Mr. Fox:

The Food & Drug Administration (FDA) has reviewed your labels for several of your juice drink concentrates including Mango BANG-O, Lemon OLE!, Orange OLE!, and Grape OLE!, which were collected by Investigator Audrey Uy during her inspection of your firm on January 15 and 19, 1999. Our review reveals that these labels cause the above products to be misbranded under section 403 of the Federal Food, Drug and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21CFR), Part 101 – Food Labeling, as follows:

1. The above products declare that they contain certified artificial colors in their ingredient statement but they fail to list the actual name of each certified color used in the production of these products as required by 21 CFR 101.22(k)(1), e.g., FD&C Yellow #5. Analysis of the above products found the following certified colors:

Mango BANG-O contains FD&C Yellow No. 5, Yellow No. 6 and FD&C Red No. 40.
Lemon OLE! contains FD&C Yellow No. 5.
Orange OLE! contains FD&C Yellow No. 6.
Grape OLE! contains FD&C Red No. 40 and FD&C Blue No. 1.

2. The products Mango BANG-O, Lemon OLE!, Orange OLE! and Grape OLE! are misbranded because they purport to be beverages that contain fruit juice, but fail to provide a statement of the total percentage of fruit juice contained in each as required 21 CFR 101.30(b)(1).

We noted that the products do not bear nutrition labeling and no specific information was provided regarding the consignees and uses for several of these products. If these products are sold solely to restaurants or other facilities where they will be used in food preparation and not served to consumers in the package received, the products are exempt from nutrition labeling under 21 CFR 101.9(j)(2)(iv) even if they bear nutrient content claims e.g., "Vitamin C enriched." However, if the packages are offered for direct sale to consumers, e.g., in a wholesale store, the exemption does not apply.

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The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

ADDITIONAL ISSUES:

Additional comments with regard to the aforementioned labels that we would like to bring to your attention at this time are the following:

- A. The name and address should appear together in one place on the label.
- B. The term "Natural Flavor" that appears as a separate claim in an 'orange star burst' on the Orange OLE! is misleading because the product label also declares artificial flavor.

If you have any questions relating to this letter you should contact Robert B. McNab, Compliance Officer, at (949) 798-7709. Your written reply should be directed to:

Mr. Thomas L. Sawyer, Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

Sincerely,



Thomas Allison
Acting District Director
Los Angeles District

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief