



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35  
Public Health Service

Central Region

M33251

Telephone (973) 526-6002

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

December 30, 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Daniel C. Jang  
President  
Raphah, Inc.  
12-C Jules Lane  
New Brunswick, New Jersey 08901

FILE NO.: 00-NWJ-15

Dear Mr. Jang:

We inspected your firm located at 12-C Jules Lane, New Brunswick, New Jersey, on November 3 and 8, 1999. During the inspection our investigator collected copies of your labeling. Review of your labels found serious violations of the Federal Food, Drug, and Cosmetic Act (The Act) and Title 21, Code of Federal Regulations, Part 101, Food Labeling (21 CFR Part 101) with regard to labeling of food products.

Your citrus juice products are misbranded within the meaning of Section 403(a)(1) and 201(n) of the Act because they do not comply with the labeling requirement that juices not specifically processed to prevent, reduce or eliminate the presence of pathogens bear the warning statement set forth in 21 CFR 101.17.

During the inspection of your firm, our investigator also documented additional serious violations of current Good Manufacturing Practices (cGMPs) for human food (21 CFR Part 110). The violations were presented to your firm's attention on a FDA-483, List of Inspectional Observations, at the close of the inspection on November 8, 1999. The cGMP violations cause your products to be adulterated within the meaning of Section 402(a)(1) of the Act.

The significant observations are:

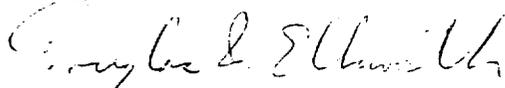
1. Your firm has no documentation that the producer of the unpasteurized juice base concentrates, which is used to manufacture the finished Natural Orange Juice, Natural Fruit Punch, and Natural Pink Grapefruit Juice Drinks, has validated and verified that the production processes result in a 5-log reduction in the pathogen of greatest concern. The firm failed to provide the required warning statement on their label, "WARNING: this product has not been pasteurized and, therefore, may contain harmful bacteria that may cause serious illness in children, the elderly and persons with weakened immune systems," to reflect the fact that the juice was not pasteurized.
2. Your firm has not performed any testing and/or validated the processing step for microwave dry powdered ingredients prior to manufacturing. There is no assurance that the microwaved ingredients retain their potency and efficacy.
3. Failure to clean the vitamin tableting/packing/counting machines between each production run or at the end of each day to prevent residual powder buildup on the surfaces of the equipment.
4. The bottling line was observed to have a large buildup of old product residue and dust on the bottle feeder.
5. Your firm stores their vitamin powder directly on the floor in unsealed drums. The plastic liner bags inside the drums were stained and encrusted with old product. The plastic scoops lying inside the drums were scarred and encrusted with old product.
6. The ceiling, which is directly over the blending tank in the processing room/area, was missing several portions. There was plastic sheeting tacked up over the entire ceiling area to prevent debris falling from the joist/rafter areas into the processing area.
7. The processing/packing room floors were worn. There were broken tiles and missing tiles in several areas, and a large buildup of old product residue on the floor.
8. The hose bibs and hose lines were not protected with backflow preventers.

The labeling violation cited above concerns certain new labeling requirements and is not intended to be an all-inclusive list of labeling deficiencies associated with your products. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the FDA. It is also your responsibility to assure adherence with all requirements of the Good Manufacturing Practice Regulations. We request that you take prompt action to correct any noted violations not already corrected. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

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 being taken to prevent the recurrence of similar violations. 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.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



DOUGLAS I. ELLSWORTH  
District Director  
New Jersey District Office

AC:slm