



July 26, 2000

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

WARNING LETTER  
CHI-27-00

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Bradley Barnhorn, CEO  
Fantasia Fresh Juice Company  
5617 North Pearl Street  
Rosemont, IL 60018

Dear Mr. Barnhorn:

On January 26-28 and February 14, 2000, the Food and Drug Administration (FDA) conducted an inspection of your orange juice manufacturing facility. We found that you were manufacturing and distributing unpasteurized orange juice products under the following labels:

“FANTASIA FRESH SQUEEZED ORANGE JUICE”  
“FANTASIA MANGO MANGO SMOOTHIE”  
“FANTASIA TROPICAL TANGO SMOOTHIE”  
“FANTASIA ST JOHN’S BLUES BE GONE”  
“FANTASIA PROTEIN MACHINE”  
“FANTASIA POWER “C””

All unpasteurized orange juice products being manufactured and distributed by your firm under the above labels are misbranded within the meaning of Section 403(a)(1) and 201(n) of the Federal Food, Drug, and Cosmetic Act (the Act). They are misbranded because the products do not bear the warning statement required by 21 CFR 101.17(g)(2). The products are not exempt from this labeling requirement because you are not processing the juice in a manner that has been validated to achieve a 5-log reduction of pathogens.

Your firm does not have a validated 5-log reduction plan in place. Our inspection revealed that your firm did hire a consultant to write your Hazard Analysis Critical Control Point (HACCP) Plan, and that the plan is being revised. However, the HACCP plan does not achieve the 5-log reduction. You informed the FDA investigators that the 5-Log reduction was achieved in the initial sanitizing and washing of the oranges, but you did not provide records to substantiate your claim or to validate the 5-log pathogen reduction process. You claim your consultant firm conducted a study on sanitizing using chlorine dioxide, [REDACTED],” but you used peroxide instead in your process. You have not provided data to show that the peroxide used at the concentrations and contact times

specified acts the same as chloride dioxide. The [REDACTED] juice extractor manufacturer claims a 1½-log reduction at this processing step, but no information was submitted to the FDA to support this claim.

The above list of violations is not intended to be an all-inclusive list of deficiencies of your labels or of activities conducted by your firm. Other labeling violation can subject your juice products to legal action. It is your responsibility to assure that your establishment is in compliance with all requirements of federal regulations. You must take prompt action to either correct your labels by including the warning statement, or use a process that is demonstrated to consistently achieve a 5-log reduction of pathogenic microorganisms.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific actions taken to correct the noted violations including an explanation of each step taken to prevent the recurrence of similar violations. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your written response should contain the following information: 1) a copy of your new label(s), and when the label(s) will be added to the juice products or information on the validation of the 5-log reduction that your firm has in place; 2) list of all unpasteurized juice products currently in production at your facility including an estimate of how much of each product is currently in distribution; 3) where each product was distributed, and; 4) under what label each product was distributed.

Your response should be sent to Dorothy S. Stanback, Compliance Officer, at the address indicated in the letterhead.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director