



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HFI-35

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1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

AUG 31 2000

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

David R. Sperry, President
California Day-Fresh Foods, Inc.
533 West Foothill Boulevard
Glendora, CA 91741

W/L 81-00

Dear Mr. Sperry:

During an inspection of your orange juice manufacturing facility located at 533 West Foothill Boulevard, Glendora, CA conducted April 18 to May 2, 2000, we found that you caused to be manufactured and distributed unpasteurized (i.e., not heat treated) orange juice products under the following labels:

"[REDACTED] Juice Fresh Squeezed Orange"
[REDACTED] Fresh Orange Juice"
[REDACTED] JUICE Blood Orange Juice".

Our investigation revealed that your firm manufactured and distributed unpasteurized orange juice, specifically product coded with "USE BY [REDACTED]", that was adulterated under section 402(a)(1) of the Food, Drug and Cosmetic Act (the Act) because the juice was contaminated with the pathogenic bacteria *Salmonella* which may render the juice injurious to health. Health officials linked consumption of your unpasteurized orange juice to an outbreak of *Salmonella* serotype Enteritidis within the United States. When notified, you conducted a voluntary recall of the adulterated product from the marketplace and temporarily ceased manufacture and distribution of unpasteurized orange juice to prevent further illnesses. We acknowledge your action in this regard.

Furthermore, information was gathered during our investigation regarding your use of a contract manufacturer that had been identified by your firm as having potential GMP violations that adversely affected their ability to manufacture juice under a 5 log microbial reduction manufacturing process. While your firm did take several positive steps to address your findings, you did not adequately assess the effect of the contract

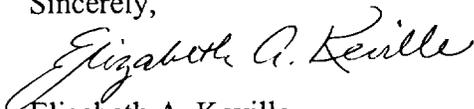
manufacturer's practices on your product. Because you could not ensure that this contract manufacturer was manufacturing orange juice using a validated 5 log reduction process, all orange juice products distributed by your firm that incorporate orange juice extracted by this contract manufacturer are misbranded under section 403(a)(1) and 201(n) of the Act because the orange juice does not have the warning statement required by Part 101.17(g), Title 21, Code of Federal Regulations (21 CFR) prominently displayed on the label. We acknowledge that you have ceased using product manufactured by this contract manufacturer in your unpasteurized orange juice products. However, we would like to remind you that you must assess any and all factors outside your validated 5 log reduction manufacturing process for their impact on the safety of your unpasteurized juice products and use this assessment in determining whether your product is in compliance with Part 101.17(g), 21 CFR. This assessment should include factors such as the purchasing of bulk juice from a contract manufacturer and transportation of bulk juice from the extractor to your facility.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Elizabeth A. Keville
Acting District Director

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