



# U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT  
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

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HEI-35

Telephone: [718] 340-7000 [EXT 5301]

## WARNING LETTER

### CERTIFIED MAIL RETURN RECEIPT REQUESTED

FEB 13 1998

Mr. Peter Nolan  
President  
Dole Packaged Foods Company  
5795 Lindero Canyon Road  
Westlake Village, CA 91362-4013

Ref: 18-NYK-98

Dear Mr. Nolan:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On December 12, 1997 FDA collected samples of packaged pineapple products at National Distribution Center warehouse located at 150 Raritan Center Parkway, Edison, NJ. These products were offered for entry into the United States through the Port of New York/New Jersey under entry number 113-1205151-6, dated November 20, 1997. Collection of a sample of Dole Brand Pineapple Chunks In Heavy Syrup (line 4-1 on the entry) revealed your firm distributed a portion of this shipment. A total of 2912 cartons (6 units x 6 lb. 10 oz. can) were distributed without receiving clearance from the FDA. A quantity of [REDACTED] cartons was contained in this shipment, evidenced by your company's fax of December 10, 1997 (copy attached) and at the time of our sample collection 3808 cartons remained in the warehouse.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA, also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

Mr. Peter Nolan, President  
Dole Packaged Foods Co.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or automatic detention to ensure that imported products are held intact until released by FDA. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Port Elizabeth, New Jersey 07201 (telephone 973-645-2386 extension 20).

Sincerely,

A handwritten signature in cursive script, appearing to read "Brenda Holman".

Brenda Holman  
District Director  
New York District Office

Enclosure: December 10, 1997 Fax