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**WARNING LETTER**

Food & Drug Administration  
Olympic Towers, Suite 100  
300 Pearl Street  
Buffalo, NY 14202

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

August 6, 1998

Messrs. Ronald and Blair Pray  
Pray's Farmers Market  
605 State Route 3  
Plattsburgh, New York 12901-6530

Ref: BUF 98-11

Dear Messrs. Pray:

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

On or about July 18, 1998, your firm imported lemons and bananas into the United States as follows:

[REDACTED]

The FDA issued a Notice of FDA Action for this entry on July 21, 1998 stating "Hold Designated." Upon visiting your firm for the purpose of sample collections on July 21, 1998, our investigation revealed portions of each lot had been distributed and were not held intact. 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 the FDA, also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without future notice such as seizure or automatic detention to ensure that imported products are held in tact until released by the FDA. It is your responsibility, as the owner, importer, consignee, to ensure 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 violations, including an explanation of each step being

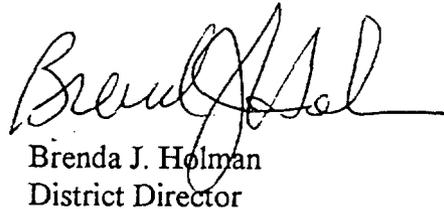
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taken to prevent a recurrence of the violation(s). Your response should be directed to Sandra K. Sylvester, Compliance Officer.

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.

Sincerely,



Brenda J. Holman  
District Director

cc:

