

4/28/97
efFood and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809**CERTIFIED MAIL**
RETURN RECEIPT REQUESTEDRef: FDA Sample No. 3109826
Customs Entry No. Informal Entry
Product: Fresh Papayas**WARNING LETTER**

FLA-97-35

April 4, 1997

Jose Medina, Manager
American Fruit & Produce Corporation
1344 N.W. 23rd Street
Miami, Florida 33142

Dear Mr. Medina:

The Food and Drug Administration (FDA) attempted to examine a shipment of fresh papayas offered for entry into the United States by your firm on March 23, 1997, under the above referenced entry number, and found that the shipment was not held intact for FDA examination. The FDA inspector observed that there were only 129 cartons available for sampling from the declared entry of 550 cartons. Regulation, Title 21, Code of Federal Regulations (CFR), Part 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to require formal entries on all future shipments imported by your company (copy enclosed).

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 of future shipments. 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.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Mr. Jose Medina
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Your written reply should be directed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen/edt

Douglas D. Tolen
Director, Florida District

Enclosure