



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Maloon
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No. 577-1277829-9
Fresh Bananas

APR 29 1999

WARNING LETTER

FLA-99-58

Mr. Guillermo L. Rodriguez
President, Caribe Food Corporation
1695 N.W. 22nd Street
Miami, Florida 33142

Dear Mr. Rodriguez:

The Food and Drug Administration (FDA) attempted to examine a 2,660 (46,500 kg.) case shipment of fresh bananas offered for entry into the United States by your firm on March 30, 1999, under the above referenced entry number, and found that the shipment was not available for FDA examination. Our inspector visited your firm on April 19, 1999, based on information supplied to us by your broker that the entry was ready for inspection. Upon arrival at your facility, our inspector was advised that the product had already been distributed. Regulations, Title 21, Code of Federal Regulations (21 CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the product was not made available to us for examination we have requested the U. S. Customs Service (Customs) to order redelivery of the fresh bananas which have been distributed without a release from FDA (copy of the redelivery order is enclosed).

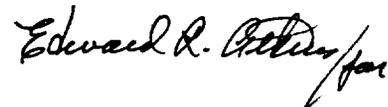
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of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

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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. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is written in a cursive style with a long, sweeping tail on the final letter.

Douglas D. Tolen
Director, Florida District

Enclosure