



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
466 Fernandez Juncos Avenue  
Puerta De Tierra  
San Juan, Puerto Rico 00901-3223

May 11, 2001

**WARNING LETTER**  
**SJN-01-09**

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

Mr. Angel Luis Martinez  
Owner  
Frigorifico Don Luis  
S-31 Mendez Pidal, El Senorial  
San Juan Puerto Rico, 00926

Product: Fresh Avocado 229/28 cartons/lbs.  
FDA/Customs Sample/Entry No: 438-0111656-7

Product: Fresh Coriander 175/50 sacks/lbs.  
FDA/Customs Sample/Entry No: 438-0110459-7

**FEI #: 300122652**

Dear Mr. Martinez:

The Food and Drug Administration (FDA) attempted to examine two shipments, one of fresh coriander and one of fresh avocado, offered for importation into the United States by your firm on or about February 6, 2001, under entry number 438-0110459-7 (coriander) and April 9, 2001, under entry number 438-0111656-7 (avocado). We found that the shipments were not held intact pending receipt of "May Proceed", and/or made available for FDA examination. On April 12, 2001, our inspector visited your firm, to examine the shipments and was informed that these products had been distributed without an FDA release.

This is a violation of Section 801 (a) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 1.90, which 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 avocado and fresh coriander which have been distributed without a release from FDA (copy of the request is enclosed).

A. Martinez  
Page 2

05/11/01

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 (the Act) and the regulations promulgated thereunder.

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

Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos I. Medina, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901.

Sincerely,

  
Mildred R. Barber  
District Director