



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 Seniorial
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).

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,

A handwritten signature in cursive script that reads "Mildred R. Barber".

Mildred R. Barber
District Director