



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Southwest Import District  
4040 North Central XPY  
Suite 300  
Dallas, Texas 75204  
Telephone: (214) 253-5200  
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May 22, 2003

Ref: FY03-SWID-WL-010

**WARNING LETTER**

**VIA FED-EX**

Donald Palmer, President  
Morven Partners, LP  
9210 Arboretum Parkway, Suite 100  
Richmond, VA 23236

Dear Mr. Palmer,

The Food and Drug Administration (FDA), on 3/4/03, was informed by Ms. Chaga Villanueva, of Brown, Alcantar & Brown, Inc, El Paso, TX, your broker for entry 328-0332606-8, line 1/1, that the entry was not held intact by your firm pending FDA review and release. On 4/23/03, the FDA was informed by US Customs and Border Protection that this entry was not redelivered pursuant to a Demand for Redelivery and that your firm was in violation of the entry bond agreement.

Entry Number 328-0332606-8 1/1, shelled pecans, [REDACTED] was imported into the United States by your firm on 12/5/02. The entry was detained under Food, Drug and Cosmetic Act 21 USC 342(a)(1) and 381(a)(3) in that FDA laboratory analysis found *Salmonella*; additional charges included 21 USC 343(b) and 381(a)(3) in that the pecans were offered for sale under the name of another food, "AZUCAR REFINADA" (refined sugar); and, 21 USC 343(f) and 381(a)(3) in that the required label or labeling was not in English. This detention status and the violations were communicated to you through our Notice of FDA Action, dated 1/7/03, a copy of which is enclosed.

On 1/29/03, FDA Compliance Officer Catherine Vieweg contacted Ms. Villanueva and asked about your firm's intended actions regarding this detained shipment. Ms. Villanueva replied that your firm intended to export the product. C.O. Vieweg responded on 1/29/03:

This is a significant health hazard in a ready to eat food...At the very least I would expect the FDA to inform Mexico that the pecans might be exported to Mexico. In the past, when we had made such notification, Mexico has refused to accept the product.

Ms. Villanueva responded that you would be informed and C.O. Vieweg would be contacted back with your intentions. Since no response was received, C.O. Vieweg contacted Ms. Villanueva on 2/24/03 again asking your intentions. Ms. Villanueva responded that the information would be provided on that same day (2/24/03). The response was finally received on 3/4/03 from [REDACTED] (where you had held the pecans in question) informing FDA that the goods had already been exported to Mexico. However, the reported exportation occurred without being overseen by either FDA or Customs. The documentation your firm presented to substantiate the purported exportation reflects that [REDACTED] of pecans with a total weight of [REDACTED] were exported. This exportation cannot be reconciled with your entry of [REDACTED] of pecans, total weight of [REDACTED].

Failure to hold an entry intact pending an FDA release is a violation of 21 CFR Section 1.90, which requires the importer to hold a sampled imported article intact pending a release notice from FDA.

Failure to promptly correct this situation and prevent future premature distribution of imported products may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs and Border Protection, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

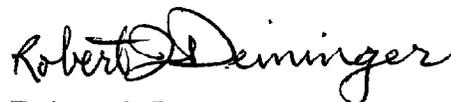
It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We have requested that U.S. Customs and Border Protection order redelivery of the goods which were distributed without a FDA release. Failure to redeliver the entire shipment to Customs custody may result in assessment of liquidated damages at a later date.

We request a response in writing within fifteen(15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent recurrence. In the event that the product is still available for examination, 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: Catherine L. Vieweg, Compliance Officer, Southwest Import District, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204.

Sincerely,



Robert J. Deininger  
District Director