



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration  
Atlanta District Office**

g1336d

**60 8th Street, N.E.  
Atlanta, Georgia 30309**

May 25, 2001

**VIA Federal Express**

Rigoberto Rimenez  
580 Mainstreet  
Palmetto, GA 30268

Ref: Customs Entry No. J50-0057225-3 (FDA Entry No. XXX-0034524-0)  
Products: Shampoo, Deodorant, Cough Syrup, and Toothpaste

**WARNING LETTER**

(01-ATL-46)

Dear Mr. Rimenez:

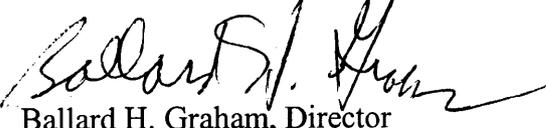
The Food and Drug Administration (FDA) attempted to examine a shipment of Shampoo, Deodorant, Cough Syrup and Toothpaste on March 16, 2001. The shipment was offered for entry into the United States on January 30, 2001, under the above reference entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21 CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the shipment was not held intact we are hereby requesting U. S. Customs Service (Customs) to order redelivery of this shipment.

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 further 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 outlining the specific steps you have taken to correct the violation. Your response should include 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 directed to the Food and Drug Administration, Atlanta District Office, 60 8<sup>th</sup> Street N.E. Atlanta, GA 30309, Attention: Karen Y. Dodson, Compliance Officer.

Sincerely,

  
Ballard H. Graham, Director  
Atlanta District

cc: Port Director  
U.S. Customs Service  
4341 International Parkway  
Suite 600  
Atlanta, GA 30354

Atlanta Customs Brokers  
650 Atlanta South Parkway,  
Suite 250  
Atlanta, GA 30349