



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland Florida 32751  
Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA FEDERAL EXPRESS**

Reference: Customs Entry No. KG2-0505994-5  
Product: Stoneware Mugs

**WARNING LETTER**

**FLA-02-14**

November 9, 2001

Mr. Ricardo J. Arias, President  
F.A.V. International Corp.  
5255 - 165<sup>th</sup> Street  
Miami, Florida 33014

Dear Mr. Arias:

The Food and Drug Administration (FDA) attempted to sample a shipment of stoneware mugs in accordance with our notice of sampling dated, September 21, 2001 under entry number KG2-0505994-5 and found that the entire shipment was not available for FDA examination. Title 21 Code of Federal Regulations Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U.S. Customs Service (Customs) to order redelivery of the unavailable portion of the entry.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of further shipments. 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 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 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: Christine M. Humphrey, Compliance Officer, 6601 NW 25<sup>th</sup> Street, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal stroke at the end.

Emma R. Singleton  
Director, Florida District