



MAISEN

**VIA FEDERAL EXPRESS**

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

Ref: Customs Entry No. 110-2809555-1  
Product: Manometers and Stethoscopes

**WARNING LETTER**

**FLA-00-92**

August 29, 2000

Gloria Festa, Supervisor  
MD International, Inc.  
7324 S.W. 48<sup>th</sup> Street  
Miami, Florida 33155

Dear Ms. Festa:

The Food and Drug Administration (FDA) requested to examine the above referenced shipment offered for entry into the United States by your firm on July 4, 2000, and has received no documents identifying the location of the entry. 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 no response has been received to our requests for documents, we have requested the U. S. Customs Service (Customs) to order redelivery of this shipment.

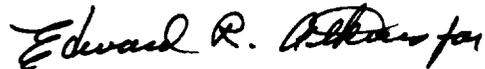
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements 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.

Gloria Festa  
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Your written reply should be addressed to the Food and Drug Administration,  
Attention: Paul Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami,  
Florida 33159-2256.

Sincerely,



Emma R. Singleton  
Director, Florida District

Enclosure

cc: Thomas Winkowski  
U. S. Customs Service  
P. O. Box 02-580  
Miami, Florida 33102-5280

Fritz Companies, Inc.  
10000 N.W. 25<sup>th</sup> Street  
Miami, Florida 33186