

**VIA FEDERAL EXPRESS**

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

Ref: Customs Entry No.: 110-0940880-7
Product: Pasta Alimentari

WARNING LETTER**FLA-00-46**

April 7, 2000

Achille Scialoia, President
Natura Mediterranea
10219 General Drive
Orlando, Florida 32824

Dear Mr. Scialoia:

The Food and Drug Administration (FDA) attempted to examine a shipment of pasta alimentari offered for entry into the United States by your firm on December 28, 1999, under the above referenced entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21CFR), 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 product was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the food products which have been distributed without a release from FDA (copy enclosed).

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.

Achille Scialoia
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Your written reply should be addressed to the Food and Drug Administration,
Attention: Timothy J. Couzins, Compliance Officer, 555 Winderley Place, Ste.
200, Maitland, Florida 32751, telephone no. (407) 475-4728.

Sincerely,



Edward R. Atkins
Acting Director
Florida District

cc: Entry Division
U. S. Customs
1624 E. 7th Avenue
Ste. 101
Tampa, Florida 33605

Fritz Companies, Inc.
8870 Boggy Creek Rd.
Ste. 700
Orlando, FL 32824