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**VIA FEDERAL EXPRESS**Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751Ref: Customs Entry No. 315-8118536-5  
Product: Tylenol Caplets & Perfumery Products**WARNING LETTER**

FLA-00-74

August 1, 2000

Ms. Kim Chin  
FX Worldwide Corporation  
5000 S.W. 72<sup>nd</sup> Avenue  
Miami, Florida 33155-5528

Dear Ms. Chin:

The Food and Drug Administration (FDA) attempted on July 20, 2000, to examine a shipment of Tylenol caplets and perfumery products offered for entry into the United States by your firm, under the above referenced 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 product was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of this shipment which has 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.

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Your written reply should be addressed to the Food and Drug Administration,  
Attn: Carlos W. Hernandez, 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

Union Transport Corporation  
3018 N.W. 72<sup>nd</sup> Avenue  
Miami, Florida 33122