



m3825n

VIA FEDERAL EXPRESS

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

Ref: Customs Entry No.: 231-1567270-3
Product: CD Player Combination System

WARNING LETTER

FLA-00-59

June 5, 2000

Mr. Peter J. Pestillo
Chairman/President/CEO
Visteon Systems, LLC
17101 Royunda Drive
P. O. Box 6098
Dearborn, Michigan 48121-4084

Dear Mr. Pestillo:

The Food and Drug Administration (FDA) attempted to examine a shipment of CD player combination systems offered for entry into the United States by your firm on May 20, 2000, 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 CD player combination systems 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.

Mr. Peter J. Pestillo
Page 2
June 5, 2000

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, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



Edward R. Atkins
Acting Director
Florida District

Enclosure

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

Expeditors International
Beacon Industrial Park
10814 N.W. 33rd Street
Ste. 115
Miami, Florida 33172