

**VIA FEDERAL EXPRESS**

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

Ref: Customs Entry Nos. 510-5460583-0 and 510-5460699-7
Multi-Sign Monitors and Pulse Oximetry Monitors

WARNING LETTER**FLA-01-25**

January 4, 2001

Mardin Varela, Director
Nova Medical Systems
6414 N.W. 82nd Avenue
Miami, Florida 33166

Dear Mr. Varela:

The Food and Drug Administration (FDA) attempted to examine two separate shipments of monitors referenced above. These monitors were offered for entry into the United States by your firm on September 11, 2000 and October 30, 2000, respectively, and were 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 shipments were not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of these two shipments that were distributed without a release from FDA (copies 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 future 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 this violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the products are still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Mardin Varela
Page 2
January 4, 2000

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Emma R. Singleton".

Emma R. Singleton
Director, Florida District

Enclosures

cc: Nippon Express
1590 N.W. 82nd Street
Miami, Florida 33126

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