



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/16/01

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland Florida 32751
Telephone: 407-475-4700
FAX: 407-475-4768

VIA FEDERAL EXPRESS

Ref: Customs Entry No: FR1-00104897
Latex Examination Gloves

WARNING LETTER

FLA-02-05

October 16, 2001

Luis Candelario, President
Nipro Medical Corporation
3150 NW 107 Ave
Miami FL 33172-2188

Dear Mr. Candelario:

The Food and Drug Administration (FDA) attempted to examine [REDACTED] cases of latex examination gloves on September 25, 2001 under entry number FR1-0010489-7 and found that [REDACTED] cases were not available for FDA examination. Title 21 Code of Federal Regulations Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We requested the U.S. Customs Service (Customs) to order redelivery of this shipment (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.

Your written reply should be addressed to the Food and Drug Administration, Attention: Christine M. Humphrey, Compliance Officer, 6601 NW 25th Street, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



for

Emma R. Singleton
Director, Florida District

Enclosure

cc: Port Director
U. S. Customs Service
P. O. Box 52-2207
Miami, Florida 33152-2207