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VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751Ref: Customs Entry No.: JN7-0300428-1
Product: Ulti-Lance**WARNING LETTER****FLA-01-45**

March 16, 2001

Abraham W. Chames, M.D.
Medical Director
Oxy-Stat Inc. Home Health Care
1841 N.E. 146th Street
North Miami, Florida 33181

Dear Dr. Chames:

The Food and Drug Administration (FDA) attempted to examine a shipment of Ulti-Lance (automatic lancing device) offered for entry into the United States by your firm on January 12, 2001, 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 the entire entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the entry was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the entry that has been distributed without a release from FDA (copy enclosed).

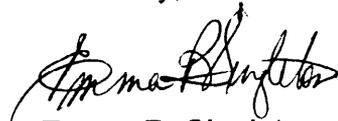
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements 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.

Dr. Abraham W. Chames
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Your written reply should be addressed to the Food and Drug Administration,
Attention: Magda M. Karlsen, Compliance Officer, P. O. Box 59-2256, Miami,
Florida 33159-2256.

Sincerely,



Emma R. Singleton
Director, Florida District

Enclosure

cc: Gateway International Clearance Services
1428 N.W. 82nd Street
Miami, Florida 33126

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