DEPARTMENT OF HEALTH AND HUMAN SERVICES

93436

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 25, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-56

Sharon A. Furness, President
Furness Medical Inc.
153 North Clark Drive
Palatine, Illinois 60067

WARNING LETTER

Dear Ms. Furness:

The Food and Drug Administration (FDA) inspected your medical gas facility located at 111 Lillian Street, Salmon, Idaho, on June 11-12, 2002. Medical gases are drugs as defined by section 201(g) (21 U.S.C. § 321(g)) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products, set forth in Title 21, Code of Federal Regulations (21 CFR), Part 210 and 211. These deviations cause your medical gas to be adulterated within the meaning of section 501(a)(2)(B) (21 U.S.C. § 351(a)(2)(B)) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in compliance with CGMP.

The deviations include the following:

1. Failure to establish scientifically sound and appropriate procedures to assure that your drug products conform to standards of identity, strength, quality, and purity as required by 21 C.F.R § 211.160. No manufacturer issued operator's manual is available at your firm for the Servomex Oxygen Analyzer, Model 570A, which is used to check purity of your medical oxygen. Therefore, no assurance could be provided that the current calibration procedures are appropriate. In addition, our investigation found that your written calibration procedures state you will "ZERO the Servomex" by introducing ambient air and adjust the instrument until you achieve a reading of 21.0%. This practice is contradictory in that to "zero an instrument" means to obtain a zero reading by introducing a gas that has no oxygen.

2. Failure to establish written procedures describing the responsibilities and authorities of the Quality Control Unit (QCU) as required by 21 C.F.R. § 211.22. You have no written procedures for a QCU, nor do you have a QCU established at your facility. In addition, your production and control records are not reviewed by a QCU, in accordance with 21 C.F.R. § 211.192.

3. Failure to routinely calibrate mechanical and electronic equipment or keep records of calibration according to a written program designed to assure proper performance as required by 21 C.F.R. § 211.68. For example, your electronic thermometer was last calibrated in June 1999, the pressure gauge for the manifold filler was last calibrated in February 1997, and the vacuum gauge has never been calibrated.

4. Failure to have written procedures for and provide employees with continued training in CGMP with sufficient frequency to assure that employees remain familiar with them as required by 21 C.F.R. § 211.25(a). Our investigation found that your employee was not properly following your standard operating procedures (SOPs). In addition, your SOPs are not adequate because they do not conform to the instructions set forth in the Servomex Operator's Manual.

5. Failure to examine packaged and labeled products to provide assurance that the containers and packages have the correct label as required by 21 C.F.R. § 211.134.

6. Failure to have written procedures for handling all written and oral complaints regarding your drug products as required by 21 C.F.R. § 211.198.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. Possible actions include, but are not limited to, seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Elrand, Compliance Officer. Should you have any questions concerning this letter, Ms. Elrand can be contacted by telephone at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosure:
FDA 483

cc: Jackie Winterowd, Manager
Furness Medical, Inc., Salmon, ID
111 Lillian Street
Salmon, Idaho 83467