



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

myllc/n

Telephone (973) 526-6009

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

September 6, 2000

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPTED

Mr. Thomas D. Hersh
Chief Executive Officer
Cape Atlantic Medical, Inc.
6 Chestnut Avenue, Unit 8
Somers Point, New Jersey 08244

File No.: 00-NWJ-52

Dear Mr. Hersh:

During an inspection of your medical oxygen repacking operations, located at 6 Chestnut Avenue, Unit 8, Somers Point, New Jersey, from June 28 - 29, 2000, an Investigator from this office documented deviations from the current Good Manufacturing Practice Regulations (cGMP), Title 21, Code of Federal Regulations (CFR), Parts 210 & 211. These deviations were noted on the Form FDA 483, List of Inspectional Observations, issued to you at the close of the inspection.

Your product, Oxygen USP, is considered to be adulterated within the meaning of Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act), in that the methods used in, or the facility and/or controls used in transfilling are not in conformance with cGMPs as follows:

1. Failure to test all filling sequences for identity and strength prior to release. For example, only one cylinder is tested per filling day, rather than the first cylinder of each lot in an uninterrupted filling sequence.
2. Failure to maintain batch product and control records for filling operations. For example, prior to June 14, 2000, batch production records were not documented for any lot of compressed medical oxygen distributed by your firm.
3. Production records implemented after June 14, 2000 were found to be inadequate. For example, a review of batch records for Lots 061400-1, 061500-1, 061900-1, 062100-1 and 062400-1, found there is no documentation of pre-fill cylinder testing, pressure and temperature were

not recorded during filling and there is no documentation that labeling is checked.

In addition, batch production records were not reviewed and approved by a qualified individual, prior to lot release.

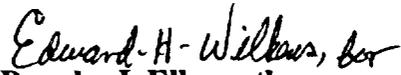
4. Failure to establish product label control or reconciliation procedures.
5. Failure to establish training programs for employees responsible for the transfilling of liquid and compressed medical oxygen.

The above list is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your medical oxygen repacking operations are in compliance with the Act and the regulations promulgated under it. You should take prompt action to implement corrections. Failure to take corrective action may result in regulatory action without further notice. These regulatory actions may include seizure and/or injunction.

We have not yet received your written response promised at the close of the aforementioned inspection. You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,


Douglas I. Ellsworth
District Director
New Jersey District

Cc: Mr. Thomas J. Newinski
In Home Medical Supply
36 Terry Drive
Trevose, Pennsylvania 19053