



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *m2585N*

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

Telephone (973) 526-6009

May 3, 1999

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Brian Nowell
President
Seaboard Welding Supply, Inc.
2112 King's Highway
Oakhurst, New Jersey 07755

File No: 99-NWJ-22

Dear Mr. Nowell:

During an inspection of your medical oxygen repacking operations, located at 2112 King's Highway, Oakhurst, New Jersey, from April 5 and 6, 1999, an investigator from this office documented deviations from the current Good Manufacturing Practice (cGMP) Regulations, Title 21, Code of Federal Regulations (CFR), Parts 210 & 211. These deviations were noted on the Form FDA483, List of Inspectional Observations, issued 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, review of filling log records for Lots 1102982, 1026981, 1014981, 0918981 and 0710984 indicate these lots were reviewed and released without being tested for identity and strength.

It should be noted that this practice was brought to your attention during the previous inspection conducted during May 21 and 26, 1998.

2. There is no verification that Bulk Liquid Oxygen meets the purity and strength required, in that incoming Lots 010499-03, 6339011799-03, 020199-1, 021899-22 and 6314-077COAA 99-02-1, were received without a Certificate of Analysis from the supplier. Additionally, the receiving records did not indicate the bulk oxygen to be USP grade, nor documented the test method used to establish the reported assay.

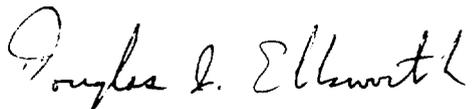
3. **Written procedures were found to be lacking, inadequate or not followed. For example:**
- a. **Procedures lack a description of operating the cascading system when used for filling oxygen cylinders.**
 - b. **There are no established procedures followed when assigning lot numbers to liquid oxygen received by the firm, for traceability purposes.**
 - c. **Complaint procedures do not describe how complaints will be evaluated and investigated. Also, equipment malfunctions, such as leaky valves, are not evaluated, as potential complaints.**
 - d. **Employee Training Procedure states that cGMP training review will occur every two years. There has been no documented training since 1995.**

The above list is not intended to be an all-inclusive of deficiencies at your facility. It is your responsibility to ensure that your medical gas 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 are in receipt of your written response to the inspectional observations, dated April 15, 1999. We are unable to comment on the adequacy of this response, since you fail to describe the steps you plan to implement in order to avoid recurrence of these violations, especially with respect to item 1. A reinspection will be necessary to verify your corrective actions and evaluate your firm's compliance with cGMPs.

You should notify this office in writing, within 15 working days of receipt of this letter, of the additional steps you have taken to ensure compliance. 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**