



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service d1484b

Purged by S. Davis 3/18/98 3/25/98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

MAR 13 1998

WARNING LETTER
98-DT-06

Ms. Jeannine Alick
Alick's Home Medical Equipment, Inc.
952 East Jackson Boulevard
Elkhart, Indiana 46516

Dear Ms. Alick:

An inspection of your medical oxygen operations was conducted on February 5 through 12, 1998 by the Food and Drug Administration.

This inspection revealed serious deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211). These deviations cause your product, Oxygen U.S.P., to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, Section 501(a)(2)(B) as follows:

1. Failure to establish a formal quality control unit including written procedures outlining the responsibilities and procedures applicable to the quality control unit, as required by 211.22. We note that you recently started having your filling employees perform a quality control check and approval/rejection of each others batch production records prior to release of the batch. This procedure would be acceptable provided the employees are properly trained to perform the assigned functions and in the requirements of the current good manufacturing practice regulations, and so long as your written quality control unit procedures adequately explained these responsibilities.
2. Failure to assure that each person engaged in your Oxygen U.S.P operations has the education, training or experience to enable that person to perform their assigned functions, as required by 21 CFR 211.25(a). Your firm has no records demonstrating that your fillers have been trained

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to perform their assigned functions and that they are familiar with the Current Good Manufacturing Practices requirements for Finished Pharmaceuticals. The lack of your employees to be adequately trained is evidenced by their lack of knowledge of the proper tests which should be performed prior to, during, and/or subsequent to filling operations and was further evidenced by the fact that they continued to fill oxygen tanks and record vacuum results in your production records despite the fact that your vacuum gauge was inoperable.

3. Failure to establish written procedures for the reconciliation of the quantities of labeling issued, used, and returned, as required by 21 CFR 211.125(c).
4. Failure to establish written procedures designed to assure that correct labels and labeling are use, as required by 21 CFR 211.130(b). Your filled cylinders bore labels from various other firms at the time of the inspection.
5. Failure to establish detailed written procedures for production and process controls covering all aspects of your oxygen operations and designed to assure that your drug products have the identity and strength they purport or are represented to possess, as required by 21 CFR 211.100(a). Specifically, your procedures do not address testing requirements, the lot numbering system, proper storage of tanks [new, returned, empty, and full], recall procedures, documenting test and inspection results, and they do not establish the frequency or responsibility for assuring proper maintenance and/or calibration of your equipment and instruments or provide for the documentation of the completion of such work.
6. Failure to establish scientifically sound and appropriate specifications and test procedures that are designed to assure that components and drug products conform to appropriate standards of

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- identity and strength, as required by 211.160(b). For example; no identity test is being performed on your incoming full cryogenic vessels and there is no record that periodic maintenance checks are being performed on your cryogenic vessels [leakage, vent, and valve checks] or production instruments/equipment in accordance with the manufacturer's directions.
7. Failure to calibrate your oxygen analyzer in accordance with the manufacturer's current directions, as required by 211.160(b)(4). Instead of the required high purity nitrogen and high purity oxygen required to zero and span the unit, you were using room air and "medical oxygen" which lacked a valid certificate of analysis documenting that the oxygen was in fact high purity oxygen.
 8. Failure to assay the incoming liquid oxygen for identity and strength prior to filling the liquid home units, as required by 21 CFR 211.165(a). If the HRC obtains bulk liquid oxygen from a bulk supplier who supplies a certificate of analysis but the test is not witnessed by the HRC, the HRC must perform an identity test on each lot received and establish the reliability of the supplier's analyses at appropriate intervals. Alternatively, no testing is required if the HRC witnesses the testing, receives a valid certificate of analysis and documents that the testing has been witnessed by the HRC. The person witnessing the testing is required to have received training specific to the analytical methodology being witnessed and this training must have been documented by the HRC.
 9. Failure to have approved master production and control records, in that your master production and control records have not been prepared, dated, and signed by one person and independently checked, dated, and signed by a second person authorized and qualified to perform such work, as required by 21 CFR 211.186(b).

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10. Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, as required by 21 CFR 211.188(b). Specifically, pre-fill or fill information for liquid oxygen or the results of temperature, hammer or valve checks for gaseous oxygen. In addition, records for 2-3 through 2-9-98 recorded a vacuum was pulled despite the fact that the vacuum gauge was inoperable during this time.
11. Failure to establish written procedures for receiving and investigating product complaints, as required by 21 CFR 211.198.

Your Oxygen U.S.P. is misbranded, in that its labeling fails to contain a statement of quantity of contents, as required by Section 502(b)(2) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 201.51.

Your Oxygen U.S.P is misbranded within the meaning of Section 503(b)(4) since Oxygen U.S.P is a prescription drug and some of your labels fail to bear the statement "Caution: Federal law prohibits dispensing without prescription".

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility as a drug manufacturer to ensure that your operations are in full compliance with all of the requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder. Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these deviations. Failure to make prompt correction may result in regulatory action without further notice, such as seizure and/or injunction.

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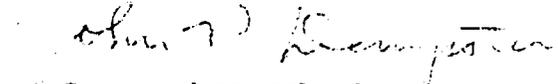
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We note that you have conducted a recall of some of your medical oxygen which was filled from February 3 through 9, 1998 and will correspond with you separately regarding your recall action.

You should notify this office, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken, or intend to take, to correct the noted deviations. If corrective action cannot be completed within fifteen working days, please state the reason for the delay and the time frame within which each corrective action will be completed.

Your response should be directed to this office to the attention of Sandra Williams, Compliance Officer.

Sincerely yours,


Raymond V. Mlecko
Acting District Director
Detroit District

copy via certified mail:
Nafe S. Alick, Director of Operations