

HFI-35/HLTH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2410m

Refer to: CFN 1124778

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

January 22, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Chris Bowman, President
American Home Medical
6946 Laurel-Bowie Road
Bowie, Maryland 20715

Dear Mr. Bowman:

The Food and Drug Administration (FDA) conducted an inspection of your Crofton, Maryland facility on January 11-12, 1999. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (CGMP), (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations included the following:

1. Failure to test finished Oxygen, U.S.P. products for identity and purity.
2. Failure to always document calibration of instruments used in the manufacture and testing of Oxygen, U.S.P. in accordance with the instrument manufacturer's instructions and/or approved procedures as follows:
 - A. [REDACTED] Oxygen Analyzer.
 - B. Pressure and Vacuum Gauges.
3. Failure to establish and implement adequate written production and process control procedures covering all critical aspects of manufacturing operations; e.g., calibration of [REDACTED] oxygen analyzer and gauges and thermometers, operation of the [REDACTED] filling operations, complaint files, recalls, distribution of finished product, quarantine and warehouse control, and expiration dating.

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4. Failure to establish accurate and complete batch production records for each batch of Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, e.g., all pre and post fill checks, temperature checks of cylinders prior to filling, heat of compression check during filling, the first leak test during filling, lot numbers, and review by a second individual for completeness and accuracy.
5. Failure to document that employees involved in filling liquid oxygen have been trained in all aspects of that operation and in current CGMP's.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gas guideline, which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 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, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,



William M. Ment

Acting Director, Baltimore District

Enclosure