

HF1-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
d1871b

Refer to: CFN 1121870

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

June 12, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert S. McFarland, Vice President
Home Health Care, Inc.
d.b.a. Commonwealth Home Health Care, Inc.
479 Piney Forest Road
Danville, Virginia 24540

Dear Mr. McFarland:

The Food and Drug Administration (FDA) conducted an inspection of your Danville, Virginia facility on May 20 - 21, 1998. During the inspection, the following deviations from Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which cause your Liquid and Compressed Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to assure that each batch of Oxygen USP conforms with appropriate specifications for identity, strength, quality, and purity that it purports or is represented to possess prior to release.
2. Failure to have the appropriate documentation that the oxygen analyzer has been calibrated in accordance with the manufacturer's instruction manual.
3. Failure to assure that each person engaged in the transfilling of compressed medical oxygen has the training in your written procedures as they relate to the employee's functions.
4. Failure to perform and or document the pre-fill, fill, and post-fill operations on each high-pressure cylinder and cryogenic vessel filled.

Mr. Robert S. McFarland

Page 2

June 12, 1998

5. Failure to establish batch production records for each batch of Liquid and Compressed Oxygen USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance and verified for accuracy and completeness by a second individual.
6. Failure to identify the oxygen container with a lot or control number that permits determination of the history of manufacture and control of the batch.

At the conclusion of the inspection, Mr. Brian P. Wilson, General Manager, was given a written list of inspectional observations (FDA-483, enclosed) which was discussed with him. We acknowledge your decision to recall from the market all lots of Liquid and Compressed Oxygen USP manufactured prior to May 20, 1998, due to the significant GMP deviations listed above. We are also in receipt of Mr. Wilson's letter dated May 27, 1998, responding to the FDA-483 observations. This response has not yet been reviewed and evaluated. Our evaluation will be communicated to you; however, in the meantime, you should not delay your response to this Warning Letter.

The aforementioned 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 document provided by FDA National Expert, Mr. Duane Sylvia, titled "FRESH AIR '98," which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please 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.

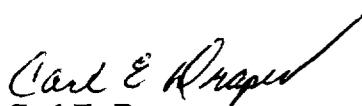
Mr. Robert S. McFarland

Page 3

June 12, 1998

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Carl E. Draper

Acting Director, Baltimore District

Enclosures

cc: Virginia Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717