

HFI-35

7/25/97
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

625

Refer to: CFN 1123112

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

July 14, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Hugh J. Doyle, III
Chief Operating Officer
Access Home Care
417 S. Lynnhaven Road
Suite 104
Virginia Beach, Virginia 22452

Dear Mr. Doyle:

The Food and Drug Administration (FDA) conducted an inspection of your Virginia Beach, Virginia facility on June 11, 12 and 19, 1997. During the inspection, deviations from the Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed which cause your Liquid 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 each batch of Liquid Oxygen to demonstrate conformance with appropriate specifications for identity, strength, quality, and purity prior to release.
2. Failure to assure that the drug product containers are suitable for their intended use, in that the cryogenic home vessels are not reexamined and their contents tested for identity after service or repair and prior to release.
3. Failure to establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

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4. Failure to establish written procedures for the production and process controls designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.
5. Failure to establish written procedures and provide documentation to assure that each person engaged in the transfilling of Liquid Oxygen has the education, training, or experience to enable that person to perform the assigned functions.
6. Failure to perform or have appropriate documentation to demonstrate that prefill operations were performed on each home cryogenic unit.

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.

We acknowledge that Ms. Carolyn Smith, IOP Coordinator, submitted to this office a response dated June 22, 1997, concerning our investigator's observations noted on the Form FDA 483. We have reviewed the response and it appears adequate. The adequacy of the corrections will be evaluated during an inspection of your facility.

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 gases 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.

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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, Ext. 14.

Sincerely,



Carl E. Draper
Acting Director, Baltimore District

Enclosure

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