



HFI-35

01/2/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1122016

d1806b
Baltimore District Office
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 11, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard M. Dinan, President
Western Medical Health System
Haystack Consolidated Services, Inc.
902 Seton Drive
Cumberland, Maryland 21502

Dear Mr. Dinan:

The Food and Drug Administration (FDA) conducted an inspection of your Sacred Heart Home Medical Equipment, LaVale, Maryland facility on April 14 and 15, 1998. During the inspection, the following deviations from the 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 test and have the appropriate documentation to demonstrate that each batch of Liquid and Compressed Oxygen USP is in conformance with appropriate specifications for identity, strength, quality, and purity it purports or is represented to possess upon receipt and prior to release.
2. Failure to calibrate the oxygen analyzer in accordance with the manufacturer's instruction manual. Your firm also fails to document the calibration of the oxygen analyzer and to maintain a certificate documenting the purity of the standard oxygen used to calibrate the analyzer.
3. Failure to perform or have appropriate documentation to demonstrate that adequate pre-fill, fill, and post-fill operations were performed on each high-pressure cylinder and home cryogenic unit filled, in that the batch production records for Liquid and Compressed Oxygen USP were not verified for accuracy and completeness by a second individual.

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4. Failure to assure that each person engaged in the transfilling of liquid and compressed medical oxygen has the education, training, or experience to enable that person to perform their assigned function. There is no documentation that employees have received GMP training and training in your facility's medical oxygen processes or procedures.
5. Failure to establish batch production records for each batch of 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.
6. 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.
7. Failure to designate a Quality Control person who has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.
8. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. Your Liquid and Compressed Oxygen USP vessels and cylinders lack a lot number that reflects each manifold filling sequence and cryogenic vessel filled.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on Form FDA-483 (enclosed). We are in the process of reviewing your response and will communicate to you our comments. However, you should not delay your response to this Warning Letter in the interim.

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 concerning 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.

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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.

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.

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,



William M. Ment
Acting Director, Baltimore District

Enclosures

cc: Mr. Richard E. Haines, Manager
Haystack Consolidated Services, Inc.
d.b.a. Sacred Heart Home Medical Equipment
Braddock Square
LaVale, Maryland 21502

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215-2299