



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

PURGED

Food and Drug Administration
 Minneapolis District
 240 Hennepin Avenue
 Minneapolis MN 55401-1999
 Telephone: 612-334-4100

October 8, 1997

cc: HFI-35/FOI Staff
 DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 5

Timothy H. Hanson
 President and Chief Executive Officer, HealthEast
 Bethesda Hospital
 559 Capitol Boulevard
 St. Paul, Minnesota 55103

Dear Mr. Hanson:

During our recent inspection of your medical gas manufacturing facility, HealthEast Med Home, Ltd. (HEMH), located at 2579 Territorial Road, St. Paul, MN, our investigators documented serious violations of the Good Manufacturing Practice Regulations (GMPs), Title 21, Code of Federal Regulations, Parts 210 and 211. Your medical liquid oxygen product is adulterated in that the controls used for the manufacture, processing, packing or holding of this product are not in conformance with GMPs, including:

Failure to witness vendor's testing of liquid medical oxygen for purity and identity after filling vehicle-mounted vessels in that no record exists to document the test has been witnessed, the test method that was used or the identity of the employees who conducted or witnessed the test. In lieu of this, HEMH does not conduct its own tests for purity or identity of incoming liquid oxygen prior to transfilling or distribution.

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Failure to properly calibrate the [REDACTED] oxygen analyzer in that there is no documentation to show that the analyzer was calibrated according to the manufacturer's instructions prior to use.

Failure to review batch records prior to release and distribution of liquid medical oxygen.

At the close of the inspection a form FDA-483 was issued to Mr. Stanley J. Yernesek, Director of Materials Management, HEMH, St. Paul, MN. Not listed on the FDA-483 but discussed with Mr. Yernesek were the following issues:

HEMH's lot numbering system fails to assure a distinctive lot number is assigned to each lot of cryogenic liquid oxygen filled in the plant. The Standard Operating Procedure directs that lot numbers be repeated when more than ten cryogenic batches are filled in one day.

HEMH's practice of assigning the vendor's lot number to liquid oxygen in vehicle-mounted vessels may cause two vehicles of liquid oxygen, filled with the same vendor's lot, to have the same lot number. They are clearly not the same batch of oxygen, e.g. lot T07H54.

Cryogenic home units are misbranded in that the labeling does not bear the following information:

1. "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal Law prohibits dispensing without prescription."
2. There is no qualifying statement such as "Manufactured by" in conjunction with HEMH's name; the sticker applied by HEMH with the firm's name and locations, lacks the state and zip code information required by 21 CFR Part 201.1(i).
3. The label has no statement of the quantity of the contents.

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This identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the GMPs. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Lawrence R. Murphy at the address indicated on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

LRM/ccl

xc: Curtis R. Merriman
Interim General Manager
HealthEast Med Home Ltd.
2579 Territorial Road
St. Paul, MN 55114