



DEPARTMENT OF HEALTH AND HUMAN SERVICES

779
11/7/98
Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

January 7, 1998

*Copy 11/7/98
JEN*

CERTIFIED--RETURN RECEIPT REQUESTED

Ms. Gayle H. Sensing, President
Medical Homecare Services, Inc.
3745 Old Hickory Boulevard
Nashville, TN 37209

WARNING LETTER NO. 98-NSV-07

Dear Ms. Sensing:

Six previous inspections of your medical oxygen gas repacking facility beginning January 1987 have resulted in four letters being issued to you describing deviations from Good Manufacturing Practice (GMP) regulations (Title 21, Code of Federal Regulations, Part 211) that cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. You responded to each one of these letters indicating that corrections had been made.

Our current inspection on November 13-14, 1997, found continuing deficiencies in your medical gas repacking operation in regard to inadequate GMP training of your personnel, inadequate and incomplete batch production records and written standard operating procedures, inadequate testing of bulk liquid oxygen and transfilled cryogenic units, and failure to verify the certificate of analysis received from your medical oxygen supplier. The inspection also revealed incorrect color coded and incomplete labels on cylinders in your storage area.

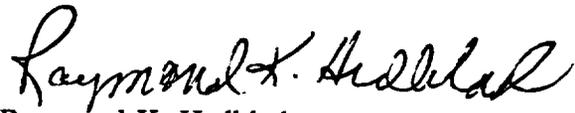
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to insure adherence to each requirement of the GMP regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against award of contracts for the affected products. Failure to promptly correct these deviations may result in regulatory action including seizure and/or injunction without further notice.

These continuing GMP regulations deviations are of very serious concern to the FDA. We are, therefore, scheduling a meeting for January 22, 1998, at 10:00 am at the Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee. We are requesting that you attend

this meeting to discuss your medical oxygen repacking operation and what changes you can make to insure that your medical oxygen is repacked in accordance with Current GMP regulations:

Please respond as to whether you will be able to attend this meeting to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 3727, telephone 615/781-5389 ext. 125, by January 16, 1998.

Sincerely,

A handwritten signature in cursive script that reads "Raymond K. Hedblad".

Raymond K. Hedblad
Director, Nashville District

RKH:JEH:mrd