



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

7/11/97
619
Burgess 7/11/97
JWA

July 11, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. Mark Waters, President
Elk Valley Professional Affiliates
220 East College Street
Fayetteville, TN 37334

WARNING LETTER - 97-NSV-12

Dear Mr. Waters:

During an inspection of your medical oxygen transfilling facility located at 660 South College, Winchester, TN, on June 11 and 19, 1997, our investigator documented deviations from the Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations, Parts 210 and 211), which cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Our inspection revealed a failure to conduct an identity test on dewars of liquid oxygen which are accompanied by a certificate of analysis, failure to perform a yearly audit of the certificate of analysis received from your supplier, failure to always document the calibration of your ~~transfilling equipment~~, inadequate written operating procedures and incomplete batch production records.

Your medical oxygen units should meet all of the labeling requirements described in the enclosed Federal Register of March 16, 1972, including your firm's address and the quantity of contents of the containers. The label should also bear the statement "Caution: Federal law prohibits dispensing without prescription."

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

Mr. Mark Waters, President - Page 2

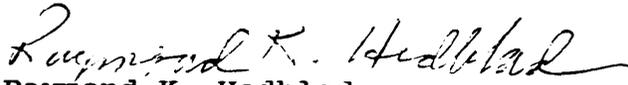
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action including seizure and/or injunction without further notice.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,


Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosures:

FDA 483
Federal Register dated 3/16/72
21 CFR Parts 210 and 211
Compressed Medical Gas Guidelines

cc: Ms. Gayle Land
Branch Manager
Mid-State Medical Oxygen and Equipment
600 South College
Winchester, TN 37398