



DEPARTMENT OF HEALTH AND HUMAN SERVICES

778
1/3/98
Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

January 6, 1998

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JEH

CERTIFIED--RETURN RECEIPT REQUESTED

Mr. Phillip W. Bradley
President
Bradley Healthcare Center, Inc.
5208 Charlotte Ave.
Nashville, TN 37209

WARNING LETTER NO. 98-NSV-06

Dear Mr. Bradley:

During an inspection of your oxygen gas repacking facility on December 3-4, 1997, our investigator documented deviations from the Good Manufacturing Practice (GMP) 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 (the Act).

Our inspection revealed no equipment to conduct required purity and identity testing on transfilled oxygen, inadequate GMP training of firm personnel, no Standard Operating Procedures, no batch production records, no master record file and no complaint file.

The inspection also determined that your facility was not currently registered with the Food and Drug Administration. Therefore, the medical oxygen transfilled by your facility is misbranded under Section 502(o) of the Act in that it is transfilled in an establishment that is not duly registered under Section 510 of the Act. Your medical oxygen also has not been listed as required by Section 510(j) of the Act. We are enclosing registration and listing forms for your use.

Your medical oxygen units should also meet all of the labeling requirements described in the enclosed Federal Register of March 16, 1972. The label should also bear the statement "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."

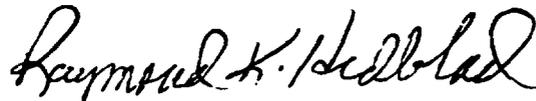
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to insure adherence to each requirement of the GMP regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against award of contracts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

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 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:JEH:mrd

Enclosures

Federal Register dated 03/16/72
21 CFR Parts 210 and 211
Compressed Medical Gas Guidelines
Form FDA 2656, Registration of Drug Establishment
Form FDA 2657, Drug Product Listing
Drug Registration and Listing Instruction Booklet