



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

446

297 Plus Park Boulevard
Nashville, TN 37217

*Guaranteed 9/24/97
JKA*

September 22, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. Jerry Jones
President
Apria Healthcare, Inc.
3560 Hyland Avenue
Costa Mesa, CA 92626

WARNING LETTER - 97-NSV-16

Dear Mr. Jones:

During an inspection of your medical oxygen transfilling facility located at 1217 South Roane Street, Harriman, Tennessee on September 4, 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 found a failure to properly calibrate your oxygen analyzer including a failure to use a standard reference gas, and inadequate supervisory review of identity test records with incomplete written operating procedures for the review of these records.

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.

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

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of each step being taken to prevent the recurrence of similar violations.

If corrective action cannot be completed within fifteen (15) working days, please 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/k1

Enclosures

FDA 483
21 CFR Parts 210 and 211
Compressed Medical Gas Guidelines

cc: Mr. Allen Gault
Branch Manager
Apria Healthcare, Inc.
1217 South Roane Street
Harriman, TN 37748