



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

November 3, 2000

Carroll
11/7/00
JLH

VIA FEDERAL EXPRESS

Mr. John A. McAbee, Sr., President
McAbee Medical, Inc.
1401 6th Avenue SE
Decatur, AL 35601

WARNING LETTER NO. 01-NSV-03

Dear Mr. McAbee:

During an inspection of your oxygen gas repacking facility on October 17-19, 2000, our investigator documented deviations from the Good Manufacturing Practice Regulations (GMPs), Title 21 Code of Federal Regulations, Part 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 that: standard oxygen and nitrogen gases were not used to calibrate your [REDACTED] resulting in no assurance of accurate oxygen cylinder/vessel assays; no Quality Control Unit; inadequate employee training in GMPs; incomplete batch production records; no documentation of the calibration of equipment used in your repacking operation and incomplete Standard Operating Procedures.

The inspection also revealed that your oxygen cylinders and cryogenic vessels failed to bear the required labeling. We are enclosing copies of proposed labels for your use.

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 product.

Mr. John A. McAbee - 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 corrections 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 directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED/kl

Enclosures: .

21 CFR Part 211
Compressed Medical Gases Guidelines
Proposed Oxygen labels