



February 22, 2002

VIA FEDERAL EXPRESS—NEXT DAY

Mr. Thomas F. Yattoni, President
Pulmonaire Service, Inc.
836 McCallie Avenue
Chattanooga, TN 37403

Warning Letter No. 02-NSV-16

Dear Mr. Yattoni:

During an inspection of your oxygen gas transfilling facility on January 9-14, 2002, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (CGMPs), 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 a failure to conduct an identity test on bulk liquid oxygen, failure to document prefill test on cryogenic home units, failure to have a certificate of analysis for the oxygen gas used for calibration of the oxygen analyzer, inadequate Standard Operating Procedures for medical gas, and inadequate Good Manufacturing Practice training of firm personnel.

The inspection also revealed that your cryogenic vessels failed to bear the required labeling. We are enclosing a copy of a proposed label and the labeling requirements as described in the Federal Register of March 16, 1972.

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

Sincerely,



Howard E. Lewis
Acting Director, New Orleans District

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Enclosures:

21 CFR Part 211
Compressed Medical Gases Guidelines
Federal Register dated 03-16-72
Proposed Liquid Oxygen label