



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

HFI-35
New 10/1/97
10/27/97
470

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-89

September 30, 1997

Hal B. Chestnut, President
Southern Respiratory, Inc.
5790 Yahl Street, Suite 101
Naples, Florida 34109

Dear Mr. Chestnut:

Inspection of your medical gas filling operation on August 14 and 18, 1997, by FDA investigator Lourdes Valentin, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed that there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that refilled cylinders of compressed medical Oxygen USP are not being adequately tested for purity and identity prior to release for distribution. Testing is inadequate in that there is no documentation to show that the [REDACTED] Oxygen Analyzer used by your firm for testing is calibrated properly as specified by the manufacturer, and there is no documentation of the testing performed.

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for calibration and maintenance of equipment, testing of filled cylinders for purity and identity, labeling, quarantine and distribution, handling of complaints, employee training or supervision. Your written procedure for receiving oxygen from a supplier is inadequate in that it specifies that the acceptable purity test must be a least 98.9% which is below the USP specification of 99.0%.

Batch production and control records are incomplete, inaccurate, and fail to document that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. It is unacceptable for a firm to use single entries on batch records to show that all significant inspections were performed on multiple cylinders. A review of batch records from April to August 1997, disclosed that the purity test documented on the records remained constant at 99.9%. Personnel reportedly recorded the test results from the supplier's invoice. Review of supplier invoices disclosed that not all of the invoices documented the analytical tests performed by the supplier. Also, the quantities of labels issued, used and returned were not recorded on the batch records, and there is no documentation that batch records were reviewed and approved by a supervisor prior to release of the products for distribution.

We acknowledge receipt of your undated response to the Inspectional Observations (FDA Form 483) issued at the conclusion of the inspection. We consider this response to be inadequate in that copies of new and/or revised written procedures were not provided for review, and we are unable to determine from your response if the constant 99.9% reading on your analyzer is being caused by improper calibration, personnel error, a need for maintenance, or that the problem has been corrected. No example of a calibration record for the analyzer was provided for review. This response does not alleviate our concerns regarding the violations documented during the inspection.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

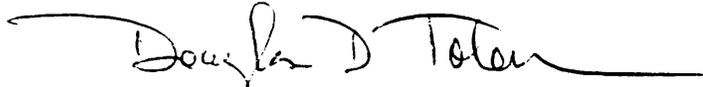
In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As president, it is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. Your response should include appropriate examples of documentation for review. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Douglas D. Tolen
Director, Florida District