



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

98-PHI-16

March 5, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas A. Young Jr., CEO
Young's Medical Equipment
3320 Nazareth Road
Easton, PA 18045

GEN.	SPEC.
RELEASE	
F# _____	DATE 3/10/98
Reviewed by: <i>Lynn J. Bonney</i>	

Dear Mr. Young:

On February 4, 9 and 10, 1998, Philadelphia District Investigator Vlada Matusovsky conducted an inspection of your medical oxygen facility located at 711 W. Main Street, Lansdale, PA. The medical oxygen filled by this facility is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act and, as such, is subject to the requirements of Title 21 Code of Federal Regulations (21 CFR).

At the conclusion of the inspection, Investigator Matusovsky issued form FDA-483, Inspectional Observations, to Harold P. Cole, General Manager, and discussed the observations with him. A copy of the FDA-483 is enclosed for your information. We have received and reviewed Mr. Rick C. Davis' letter dated February 24, 1998, written in response to the FDA-483 issued on February 10, 1998 to the Lansdale, PA, Young's Medical Equipment site. We find your corrective actions appear satisfactory for FDA-483 Inspectional Observation #1, #3, and #6, however, the responses for observation #2, #4 and #5 do not adequately address our concerns, therefore, medical oxygen manufactured by the Lansdale, PA facility is adulterated under Section 501(a)(2)(B) of the FD&C Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice (CGMP) regulations, codified at 21 CFR Parts 210 and 211 as indicated below:

1. Failure to adequately train and document training of employees engaged in the testing of medical oxygen. For example, two employees responsible for performing the identity testing on incoming liquid oxygen were not formally trained in the analytical method being used to test Oxygen, USP. Also, the firm's employees were not trained in current Good Manufacturing Practices (cGMP's) for pharmaceutical products as they relate to their assigned duties [21 CFR 211.25(a)(b)].

Mr. Davis' response does not address the issue of training in current Good Manufacturing Practices (cGMP's). This training must be conducted by a person qualified to provide training in cGMP's as they apply to your operation. The training should be documented. The trainer should be familiar with the Compressed Medical Gas Guideline and should have documentation showing their training on cGMP's and Medical Gases. We question whether the individual to whom you have delegated the responsibility of providing training to your other employees on the operation of the [REDACTED] has been adequately trained in Medical Gases and cGMP's. Further, we are very concerned that the individual responsible for the overall day to day operations at the Lansdale, PA facility did not know what cGMP's were, nor was he aware of the fact that the employees engaged in the testing and/or transfilling of medical oxygen have to be trained in them. During the inspection, the Investigator asked one of the employees responsible for performing an identity test on incoming oxygen about the minimum purity for medical oxygen. He responded the strength can be as low as 95% before the batch is rejected. If this situation occurred, your firm would be releasing product below the minimum USP specification of 99.0%.

2. Failure to follow procedure for receiving liquid oxygen units which requires the receiver of liquid oxygen to set the regulator to 2 LPM before it gets attached to the liquid oxygen unit to be analyzed for purity. The firm's employee was observed setting the regulator to 4 LPM [21 CFR 211.100(b)].
3. Calibration of oxygen analyzer, [REDACTED] medical grade oxygen instead of the required reference standard is used to perform the calibration of the oxygen analyzer prior to analyzing each liquid oxygen unit for identity [21 CFR 211.160(b)(4)].

Mr. Davis' response to these observations fail to demonstrate adequate procedures are currently being used to calibrate the analyzer and to test the incoming LOX for identity. The revised procedure submitted with the response (Attachment B), specifically, Section 3a for calibration and Section 3b for analysis, do not appear to represent the correct instructions for the use of the [REDACTED] Oxygen Analyzer. Further, Attachment D, which was submitted with your response, appears to be instructions for calibration of the Hudson RCI 6477 Oxygen Analyzer. Your firm is using the [REDACTED] Oxygen Analyzer for identity testing. We suggest that you obtain the correct operating manual and revise your procedures to reflect the instructions from that manual. A certified calibration gas is required and we recognize the Lansdale, PA facility has ordered this standard.

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Thomas A. Young

Lastly, Mr. Davis' response to FDA-483 Observation #3 appears adequate, however, we request that you identify a time frame in which a responsible and qualified individual from the Lansdale, PA facility will conduct an audit of the medical oxygen supplier.

In an effort to assist your company in coming into compliance, we are enclosing a copy of "Fresh Air '97: A Look at FDA's Medical Gas Requirements", a copy of the Compressed Medical Gases Guideline, revised February 1989 and a copy of 21 CFR 210 and 211 is also provided for your information and review. We recommend you take into consideration the deficiencies listed in this Warning Letter and proactively evaluate the compliance status of all Young's Medical Equipment sites in engaged in the manufacture and distribution of medical gases.

The above is not intended to be an all inclusive list of violations which may exist at your firm. As top management, it is your responsibility to ensure that all of your company's operations are in compliance with the Act and its associated regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. Your reply should be directed to the attention of Lynn S. Bonner, Compliance Officer, at the address noted on the letterhead.

Sincerely,


Diana Kolaitis
District Director

Enclosures

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Thomas A. Young

cc: Mr. Harvey P. Cole
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Lansdale, PA 19446

Mr. Rick C. Davis, RRT
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